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### Thesis

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## **The Changing Governance of Science?**

A critical inquiry into the contemporary politics and governance of natural science research as explored through the human tissue and embryo cases in the UK

John Gillott (BSc (Hons) Mathematics, MRes(TS))

PhD Thesis

The Open University

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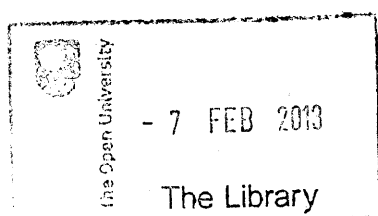
## Abstract

This thesis contributes to a theoretical understanding of change in governance of natural scientific research in the UK. The time period studied in detail is the years of the New Labour Governments, 1997 to 2010. Two case studies were chosen to explore the issues: research using human tissue and research using human embryos. Investigation was guided by these two questions:

To what extent and in what way do governance regimes incorporate proposals and approaches developed by social scientists, Science and Technology Studies and Sociology of Scientific Knowledge theorists in particular, and taken up by a range of actors in response to the perceived failures of older regimes?

What are the impacts of contemporary governance regimes on natural scientific research?

A reflexive theme and approach runs through the thesis. Aspects of SSK and social science theory are drawn upon, as a means to explore governance and as a means to critically explore social science itself. Beyond SSK, a novel reading and combination of Erving Goffman and (more critically) John Rawls is used to



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interrogate the many dimensions of the performative work of natural and social scientists who were drawn into public engagement and deliberative exercises.

The thesis finds that in some areas there has been significant change to the ways in which governance is organised and conducted, and that STS and SSK themes and approaches have contributed to this. The thesis outlines what has been lost: professional discretion; clarity about social science analysis and goals; and clarity about issues of public interest and issues associated with scientific research and knowledge. A typical outcome is greater complexity and greater bureaucrats' and managers' influence. That campaigners and STS / SSK theorists did not aim for this is largely true. That they have some responsibility for the outcome is also true.

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## Chapter One: Introduction

'The idea of making this speech has been in my mind for some time. The final prompt for it came, curiously enough, when I was in Bangalore in January. I met a group of academics, who were also in business in the biotech field. They said to me bluntly: Europe has gone soft on science; we are going to leapfrog you and you will miss out. They regarded the debate on GM here and elsewhere in Europe as utterly astonishing. They saw us as completely overrun by protesters and pressure groups who used emotion to drive out reason. And they didn't think we had the political will to stand up for proper science. I believe that if we don't get a better understanding of science and its role, they may be proved right. Let us start with the hardest thing of all to achieve in politics: a sense of balance. Already some of the pre-speech criticism suggests that by supporting science, we want the world run by Dr Strangelove, with all morality eclipsed by a cold, heartless test-tube ideology with scientists as its leaders.'

**Tony Blair, 2002**

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In 1945 Robert Oppenheimer, physicist and scientific leader of the Allies' atomic bomb project, argued that 'it is not possible to be a scientist unless you believe that knowledge of the world, and the power which this gives, is a thing which is of

intrinsic value to humanity.' (Pais and Crease, 2006, p. 51). In that same year, Vannevar Bush, head of the US Office of Scientific Research and Development, published a report entitled *Science, the Endless Frontier*. In it he envisaged endless benefits to American society from scientific advance. Science would bring jobs, rising living standards, and improvements in culture.

If the post-war period was the atomic age, with physicists in the ascendancy, today is the age of biotechnology, with biologists and information specialists to the fore. And in their eulogies for the completion of the 'rough drafts' of the human genome in June 2000, scientists and politicians made bold claims for the future, echoing the themes of Oppenheimer and Bush. Mike Dexter of the Wellcome Trust, which funded a substantial proportion of the public sector effort, described the project's significance as surpassing that of the wheel: 'I can see technology making the wheel obsolete', he said, 'but this code will be useful and used as long as humans exist.' President Clinton was similarly hyperbolic: 'with this profound new knowledge, humankind is on the verge of gaining immense, new power.'

But such apparent continuities cannot hide the fact that we all—the public, scientists and politicians—sense even if we don't fully understand that our relationship to scientific innovation has changed in the past half-century.

Compare the concerns of two leading scientists from the respective eras, Joseph Rotblat and Bill Joy. Rotblat resigned from the atomic bomb project (the Manhattan Project) in late 1944 when he learned that Germany had abandoned its attempt to make a bomb. It was a lonely step, but one which won him respect and support in the years that followed. He campaigned thereafter, for the rest of his life indeed, for scientists to sign an oath to do no harm, akin to the Hippocratic oath signed by doctors. Awarded the Nobel Peace Prize in 1995, his central focus was opposition to the obvious and possible military uses of science, and support for socially and environmentally useful alternatives.

In the same year that scientists and politicians were celebrating the completion of the rough drafts of the human genome, Bill Joy, cofounder and Chief Scientist of Sun Microsystems worried that 'the future doesn't need us' (Joy, 2000). The combination of three new technologies, robotics, genetic engineering and nanotechnology offers not just dangerous power to the wilfully destructive, but also threatens accidental catastrophe. Echoing more contemporary themes about the dangers of unforeseen events, of things running out of control, he wrote: 'This time—unlike during the Manhattan Project—we aren't in a war, facing an implacable enemy that is threatening our civilization; we are driven, instead, by our habits, our desires, our economic system, and our competitive need to know.' For Joy, who helped to develop some of these technologies, the only solution is a far broader relinquishment than that called for by Rotblat: 'to limit development of

the technologies that are too dangerous, by limiting our pursuit of certain kinds of knowledge.’ Recognising the role he played, and the possibility that the cat might already be out of the bag, he concluded, sadly, ‘henceforth, for me, progress will be somewhat bittersweet.’ (Joy, 2000).

Joy’s is an extreme voice within the scientific community, as was Rotblat’s in his day. But in a focused way they highlight shifting general attitudes. This is not to say that we are not still fascinated by science and hopeful of its potential. Indeed, numerous surveys all agree that a majority of people believe that scientific progress makes the world a better place. But we are also worried, not just about deliberate use and misuse, but also about a wider and more diffuse set of issues: the speed of developments; the unintended consequences of scientific advance; and the threat innovation may pose to the values we hold dear. Today we tend to see science as something that happens beyond our control, as likely as not driven by commercial self-interest rather than the quest for pure knowledge or social benefit. The link that Oppenheimer made—between expanding knowledge and value to humanity—is today still present, but less clearly so in the public mind. It is also a link that is less clear in the minds of some scientists themselves, or is one that they do not always proclaim from the rooftops. And for some scientists working in the area that so troubled Bill Joy, responsibility must rather be embedded in the very practices of research and knowledge production (McCarthy and Kelty, 2010).

### **1.1 The changing governance of science?**

An aspect of changing attitudes towards natural scientific research is a significant shift in the discussion of the governance of natural scientific research, one that has accelerated since the mid 1990s. In the opinion of a number of social scientists this change was particularly rapid and is particularly marked in the United Kingdom (Brown, 2009, Gottweis, 2008, Irwin, Jones and Stilgoe, 2006). The discovery in 1996 of a link between Bovine Spongiform Encephalopathy (BSE), a disease affecting cattle, and variant Creutzfeldt-Jacob Disease (vCJD), a new form of a similar disease in humans, shook the Conservative Government, which was perceived to have falsely re-assured the public about the safety of eating meat from UK cattle. This episode also, quite quickly, and with long-term effects, catalysed a transformation in public deliberation on the governance of science. Indeed, the meaning of governance itself is now different in many contexts.

Intense discussions took place in the media, civil society, academia and within Government and elite scientific circles in the years that followed. Then further to that, and in part encouraged by it, while much reflection was taking place on the appropriate Governmental and governance response in the period 1999 to 2001, further controversies erupted around genetically modified food and crops, the



safety of mobile phones and the use of human tissue in research, all of which either directly or indirectly fed back into further debate on research governance.

The political damage caused by BSE was perceived to be about the mishandling of risk and in particular risk communication. Lord Phillips' official inquiry cleared the Government of serious wrongdoing when it reported in October 2000, but it also made clear that official attitudes could never be the same again: 'The Government was preoccupied with preventing an alarmist over-reaction to BSE because it believed that the risk was remote. It is now clear that this campaign of reassurance was a mistake.' (The BSE Inquiry Report, Volume 1, p. xvii). The implication of this was that Governments should not reassure people, or seek to calm panics, for the report did not merely mean that the 'campaign of reassurance' was a mistake with hindsight. Phillips meant it was wrong full stop. This is justified in the report with the comment that 'the importance of precautionary measures should not be played down on the grounds that the risk is unproved.' (The BSE Inquiry Report, Volume 1, p. 266). In this way, the precautionary principle, or approach, became, in popular discussions, the most well known aspect of the new approaches to governance.

But the new approach is about far more than precaution. It has been characterised in a number of ways and called a number of things. For the editors of the critical investigation *The Limits to Governance*, it entails 'an increased role

of non-government actors in policy-making through various participatory networks and mechanisms.' This understanding, they go on to note, foregrounds governance as 'an inherently political process, concerned with articulating different actors' interests, values and beliefs'. (Lyll, Papaioannou & Smith, 2009a. p. 261). Simply and directly it was dubbed the 'Democratic Model' by social scientists Alan Irwin and Peter Healey in a submission to the important House of Lords inquiry into *Science and Society* (published in 2000). Ian Hargreaves, former editor of the *Independent*, has championed this framework, and argued that it should include ideas of 'socially, economically and environmentally sustainable development' and be "based largely on participatory processes in which publics (as citizens and consumers) predominate". (Hargreaves and Ferguson, 2000, p. 11).

In the immediate aftermath of BSE through to and after the controversy over GM foods and crops, critics of previous practice secured the moral high ground in public debate on issues as diverse as modern farming methods, genetic engineering, global warming and mobile phones. Jonathon Porritt, a former Director of Friends of the Earth and an advisor to both Prince Charles and Tony Blair when he was Prime Minister, believed that science would only regain trust if it became 'more precautionary; more participative; less arrogant; less compromised by its paymasters; more compassionate; and more holistic.' Porritt hoped to persuade, but suggested that we might have to 'constrain' scientists,

addicted as they are to the Promethean spirit; accustomed accordingly to 'pushing endlessly on into new territory.' (Porritt, 2000, pp. 33; 136).

But while the controversies of the time provided him with an elevated platform, Porritt feared that behind and through all the talk of change individual scientists and also Governments and scientific institutions were still wedded to the (old) values of science. In other words, while there was much talk of change and much innovation in terms of consultations and the like, regarding the big picture of Government thinking and action, and at the practical level of governance and research practice, it was business as usual, or nearly so.

A number of social scientists agree with Porritt. Starting with a critical assessment of the Phillips report into BSE (which they regard as being far too sympathetic to the Government) through to continuing opposition to the Government's in principle support for GM technology, they wonder what has in fact changed, beyond the extensive talk of change. In regard to the broad themes associated with the Democratic Model, for leading Sociology of Scientific Knowledge (SSK) theorist Sheila Jasanoff, the need to pursue change is as strong now as it always was:

'we need disciplined methods to accommodate the partiality of scientific knowledge and to act under irredeemable uncertainty. Let us call these the

technologies of humility. These technologies compel us to reflect on the sources of ambiguity, indeterminacy and complexity... This call for humility is a plea for policy-makers to cultivate, and for universities to teach, modes of knowing that are often pushed aside in expanding scientific understanding and technological capacity. It is a request for research on what people value and why they value it. It is a prescription to supplement science with the analysis of those aspects of the human condition that science cannot easily illuminate. It is a call for policy analysts and policy-makers to re-engage with the moral foundations for acting in the face of inevitable scientific uncertainty.' (Jasanoff, 2007).

There is undoubtedly much continuity in both the rhetoric and practice of governance. Regarding the rhetoric, in the UK one could point to any number of speeches by Prime Minister Tony Blair or his successor Gordon Brown celebrating natural science and its importance in a way that Porritt, Jasanoff and others would characterise as hubristic, exclusivist and deterministic (such as the one by Tony Blair I quoted from at the beginning of this chapter, and others I will refer to throughout this thesis). There is also a general sense of agreement with a point Jasanoff made in 1996, one that applies even more so today perhaps, that natural science is 'the institution that many regard as the most potent source of authority in the modern world.' (Jasanoff, 1996, p. 393).

However, while most would agree that there is a good deal of continuity, some social scientists have suggested that we should consider the possibility of substantive change when taking stock of developments over the past 15 to 20 years; substantive change that is beyond the talk of change. As Alan Irwin has put it:

'The starting point for inquiry must be to view the new scientific governance as a legitimate object of study *in itself*. Rather than contrasting current discussions with some Habermasian ideal, seeking to squeeze them into one analytical model or else dismissing them as "business as usual", it is important to approach these various statements as an expression of government thinking in the face of what is seen as a crisis of public trust in scientific institutions.' (Irwin, 2006, p. 310.)

Examining the nature of contemporary governance in the above spirit raised the question, or the difficulty, of how to analyse changes in governance and how to weigh up the role of particular factors and agents in any change. This thesis provides some answers to the latter issue as it investigates the substantive question of the scale and nature of change in governance.

A distinction needs to be drawn between different aspects or components of natural science governance. In the quote given above, Jasanoff is particularly

critical of the use of or issues associated with science as authority. It is other things as well of course; notably it is also a research activity, a practical process of inquiry and knowledge generation. There are connections, clearly – prior claims about the state of knowledge point to and are used to justify research activities; as are promissory claims about the (projected) outcomes of research. Social science investigation and critique over the past 15 to 20 years has run up and down the continuum of science seeking to open up debate. It hasn't always been clear about the issues thrown up by continuity and discontinuity. In this thesis the focus is, in particular, on the governance of natural scientific research, that is natural science as a research activity.

## **1.2 The framing of governance**

Governance is a broad topic, and it might be appropriate to use different conceptualisations in different contexts. For example Andy Stirling takes the following wide-ranging approach when focusing on opening up debates:

'The starting point for this analysis is a distinction between parallel, interlinked, and mutually coconstituting processes of commitment and appraisal in technology governance. Here, "governance" is taken to encompass the diverse totality of actors, discourses, structures, and processes implicated in guiding and shaping technological configurations

(Kooiman 1993). In these terms, appraisal is about *informing*, and commitment is about *forming* tangible social choices in the governance of science and technology.’ (Stirling, 2008, p. 265).

In related contexts but with a somewhat different focus, Lyall, Papaioannou and Smith suggest that it is rather the limits to wide-ranging notions of governance that might be most interesting and important:

‘In this and many of the chapters that follow, we consider some of the “new tools of governance” and how they might apply to the life science industries. We shall suggest that there are actually limits to the all pervasive notion of “governance” and that, instead, the multifaceted policy and regulatory situation that applies to genomics and the life sciences more generally actually argues for the existence of a government-governance continuum with different aspects of genomics technologies sitting at different points on this spectrum. Despite the political (and academic) rhetoric about new governance approaches, we perceive the enduring capacity of the state (in the North at least) to control and also to frame debates about new technology – hence “the limits to governance”.’ (Lyall, Papaioannou and Smith, 2009, p. 3).

The focus one chooses and the concepts one reaches for may appropriately be influenced by circumstances, but there is always a choice. Stirling's point about the relationships between commitment and appraisal, forming and informing, and the comment about academic rhetoric in the above quote points to the issue of framing, and a particular issue highlighted by Haddow, Bruce, Calvert and Williams:

'There has been much criticism from STS colleagues about the disposition of scientists to persuade public/s that the science they are conducting is good and fair by framing the issues in a particular way. A much overlooked issue in these interactions is the problem of "framing" by the social scientists themselves.' (Haddow et al, 2009).

Arguments about how to think about the governance of science and the changing governance of science include different ideas about how to frame debates. One must pay close attention to statements that appear as or are presented as observations that might rather be viewed as framings. Relating to one of my case studies, consider the following observation:

'Regulatory decisions concerning hybrid forms (i.e. concerning innovations in the transfer of DNA, cells, tissue and organs between humans and animals) can have profound epistemic and social implications insofar as



they challenge our commonly held conceptions about what is human and what is animal... In this article, we critically examine how regulatory institutions in the UK respond to the challenges to human identity posed by xenotransplantation and cybridization.' (Haddow et al, 2010, pp. 4-5)

This is a good example of an apparent comment on governance and ethics, that is in fact loaded with the authors' own assumptions about governance and ethics. To take one of the examples they study: cybrids, that is very early stage embryonic masses created by transferring a human cell nucleus into an enucleated animal egg. These need have no epistemic or social implications, still less 'profound' ones, if one makes the distinction, as many people surely do, between cellular life and humans and animals existing as living and breathing entities in the world. At the end of the article, under the heading 'But not animal enough to be animal', they discuss the problem of trying to define species in terms of their genetic composition, pointing out that there aren't such things as human genes etc. But doesn't this count against the argument presented in the above quote? They then go on to conclude the main section of the article in this way:

'UKXIRA (or a similar organization) could be reconvened and given a permanent standing committee (as was originally intended) with a remit that would include all animal-human fusions. Insomuch as this would bring

equilibrium back to the “regulatory” and “organic” body balance, as shown in Figure 1, it would also avoid real or perceived transgressions between what is considered animal and what is considered human given the rapid, and often unpredictable, pace of change in this area. To all intents and purposes, experience, independence, public consultation and open governance are required in an area that has the potential to bring back the mythological creatures of the past.’ (Haddow et al, 2010, p. 15)

Isn't their commentary encouraging the revival of mythical thinking? Three of the authors of this article were coauthors with Williams of the comment I quoted from immediately beforehand on the problem of framing by social scientists. This juxtaposition of the two pieces suggests that while vigilance is required, framing is also inescapable in large part. The issue is how to examine and think about framings – both those of others and one's own.

The issue of framing is no less important in the other case study I used, the governance of research using human tissue. Mary Dixon-Woods et al present a far more positive view of public attitudes towards research than is often the case in the social science literature, and make some important observations in the course of challenging other framings:

'Claims about the views and feelings of "the public" are increasingly important in bioethical and policy debates, and are influential in the regulation and governance of bioscience. The organ retention controversies and associated media coverage (Seale, Cavers and Dixon-Woods, 2006), for example, led directly to the UK Human Tissue Act 2004 (McHale et al., 2007), while earlier guidance issued by the Medical Research Council (2001) and a report by Nuffield Council on Bioethics (1995) on use of human tissue for research can also be seen as an attempt to respond to address perceived public concerns. In this article, we argue that a large body of academic literature, primarily within bioethics and the social sciences, has also been active (activist, even) in its commentary on use of human tissue for research purposes, and has tended to depict "public opinion" as overwhelmingly negative.' (Dixon-Woods, Wilson, Jackson, Cavers and Pritchard-Jones, 2008, p. 58).

They go on:

'Public views are then seen as supplying the imperative for wholesale overhaul of regulatory structures, the better to reduce opportunities for opportunism, exploitation and repugnance... A coalition of legal and ethical scholars, anthropologists and social scientists has thus begun *speaking for* those who contribute tissue for research purposes, and

*speaking for “the public” more broadly conceived.’ (Dixon-Woods, Wilson, Jackson, Cavers and Pritchard-Jones, 2008, p. 61).*

I agree with much of their argument, and discuss it further in chapter five.

However, a limitation of their analysis is that it draws upon, without fully acknowledging the framing this creates, the views of family members of a child with cancer; just the kind of people who tend to be favourably disposed towards research.

Others have investigated the different perspectives that are generated when distinctions are made between specific interested groups and the public more generally. Mike Michael considers the Public in General (PiG) and Publics in Particular (PiP) as categories that interact with each other and science, one theme being that PiP often define themselves against the fickle or uninformed PiG. He also at the same time writes a good deal about how the categories are defined by others, including social scientists. Of particular interest to me in my work was his observation that one of the most basic framings within contemporary theories of governance is that publics in general as well as publics in particular have a desire to deliberate, participate and engage:

‘Here, however, we shall attend to the ways in which versions of the PiG are presumed in the very project of “giving voice” in PES. As noted above, it is

assumed that the PiG has an in-principle political capacity to deliberate, to participate, to engage. But, it is also assumed that there is some deep-seated *desire* in the PiG to deliberate, to participate, to engage. Such a desire might be suppressed, or diverted, or dissipated, but nevertheless by virtue of the tacit characterization of the PiG as “citizenly,” it can come to define the PiG.’ (Michael, 2009, p. 622)

A related framing that I discuss more in later chapters is that older notions associated with the idea of scientists having a ‘freedom to research’ are widely considered to be no longer tenable. Both of these framings – that publics of different kinds but especially PiG have a deep-seated desire to participate and that ‘freedom to research’ is no longer tenable – are as widely held as they are in part because the pro-active social science research community was very active in framing debates according to their views over the period considered in this PhD, the years of the New Labour Governments.

### **1.3 The research questions**

This PhD thesis investigates critically the nature of some aspects of the governance of natural scientific research in the UK through an analysis of two contentious and connected case studies: human tissue and human embryology. The time period covered is largely the New Labour years, 1997 to 2010, with

some spillover into the years either side of those dates. Some comparisons are also made with earlier periods. The thesis as a whole looks at the following two, related, questions:

To what extent and in what way do governance regimes incorporate proposals and approaches developed by social scientists, STS and SSK in particular, and taken up by a range of actors in response to the perceived failures of older regimes?

What are the impacts of contemporary governance regimes on natural scientific research?

I conclude that while there is much continuity between old and new forms of natural science research governance, there have been changes, and that some of these changes are the result of the work of various actors, including some STS and SSK theorists, in championing aspects of the Democratic Model.

In developing this argument I engage with some policy makers' and some natural scientists' sense that things have indeed changed, partly for the reasons I outline. I also engage with theorists who have looked at the same issues and come to different conclusions. In particular I engage with the radical strand in STS and SSK. As a counter-hypothesis to both my own and that of radical STS and SSK I

also engage, to a lesser extent, with Finlayson, Thorpe and Gregory's characterisation of the New Labour years that links ideas of democratisation and participation to different roots and ambitions to the ones drawn on by STS and SSK.

The first analysis, that of radical STS and SSK, is outlined and discussed in more detail in chapter two in particular and chapter three to a limited degree, but to consider it briefly here: as we saw in section 1.1 above, Sheila Jasanoff believes that the radical agenda pursued by some in STS and SSK is still very relevant and important. Leading STS and SSK scholar Brian Wynne, who has worked with Jasanoff and pursued similar themes over the past two decades (and more), agrees. And a principal reason it is so important still is that he believes little has changed. More than this, he is surprised that anyone could think otherwise, and he is positively bewildered that anyone could think that his ideas have brought about any change. He concludes his article 'Dazzled by the Mirage of Influence?' with this observation:

'My most striking personal experience of STS engagement in policy worlds has been sheer disorientation at my failure to recognize my own ideas in what has been celebrated as my work's public influence. In the very process of taking on influence, we are reinterpreted in ways that of course we don't control, and may not accept nor even understand. The next

question hovers: can STS influence its own “influence,” to limit its transformation into alien goods? Once started, the agony continues.’ (Wynne, 2007, p. 501).

In a sense Charles Thorpe and Jane Gregory agree with Wynne (Thorpe and Gregory, 2010; Thorpe, 2010). However, drawing on Alan Finlayson (2003) their particular argument is not that nothing has changed, but rather that there has been change but that this has little or nothing to do with Wynnian SSK.

Discussing participation in particular, they argue that some STS and SSKers might be right in thinking that participation hasn’t worked out as they’d hoped, but that’s because participation had more than one root, and other approaches did have an impact. Their thesis is that post-Fordist theorising, developed by Charles Leadbeater in particular, and pursued in more recent times by the think-tank Demos, connected up with strands of thinking developed by sociologist Anthony Giddens in particular and others influential upon the New Labour project, resulting in the Blairite enthusiasm for science and technology illustrated by the quote with which this chapter opens. In that sense participation really was quite transformative: technology preparing the market through influencing consumption, and consumers themselves changing the way innovation works. But it was not participation as understood within a concept of the Democratic Model held by the Wynnian strand of SSK.



## **1.4 Motivation, methods and approach in my research**

Up until the end of 2005 I was, through my job with Genetic Interest Group (now called Genetic Alliance UK, [www.geneticalliance.org.uk](http://www.geneticalliance.org.uk)), a participant in policy debates on the case studies. At the time I was familiar with some STS and SSK writings, and in the course of my work had met some activists for whom these writings were influential. Part of my motivation for researching and writing this thesis was to try to make some connections between what I perceived at the time to be two-way influences between some of the arguments and activities of activists and academics associated with STS and SSK on the one hand, and the worlds of policy and politics on the other. After leaving GIG I continued to follow developments, attend some events and conferences and occasionally write on some of the issues addressed in this thesis. In sum, in my research I drew on previous experience that, after the event, analysing my own experience, had aspects of a participant-observer approach.

I made contact with and held informal discussions with a range of natural and social scientists as background to scoping out the issues. I conducted a thorough review of relevant STS / SSK, governance writings and the academic literature on the two case studies. Specific data sources included reports of Parliamentary debates, reports from and materials submitted to Parliamentary Committee hearings, and materials held by the Department of Health that I was granted

access to; specifically responses to the key Governmental consultation leading up to the publication of the Human Tissue Bill.

Further to this research I conducted 24 semi-structured in-depth interviews with leading players in the fields under study during my doctoral research.

Interviewees were chosen to represent a diverse range of perspectives, on account of their intimate knowledge and often participation in the processes of governance I was studying and, wherever possible, because they straddled a boundary, between, for example, science and governance in the case of natural scientists who were interviewed. Interviewees included MPs, civil servants, regulators, academic social scientists, campaigners and natural scientists. The interviews lasted between 45 minutes and 90 minutes each. With two exceptions, one phone interview and one email interview, they were all conducted face-to-face. I decided to do the interviews on-the-record because I wanted to be able to discuss the specifics of the interviewees' involvement in the events under discussion, and to use specific details in the thesis. As such it would have been impossible to anonymise them effectively, and any promise of doing so would have failed to ring true, resulting in a less rather than more open and relaxed discussion. While interviewing people on-the-record may not be novel, it is certainly unusual, and I believe that combined with the methodologically reflexive approach I adopted this together may form a new way to research governance

questions that takes key agents' role in the public sphere seriously. A list of the interviewees is provided in the Appendix.

There are some similarities between the approach I took and that adopted by Alexandra Plows in her thesis, subsequently turned into a book (Plows, 2011). She used an ethnographic or participant observation approach, and interviewed some key players (though in her case these were not on-the-record). She opens the book with a discussion of frame analysis, and makes the point that her book also frames the debates in a particular way, 'by focusing on certain groups and certain issues.' This, she continues, 'is an inevitable problem to which the only solution is methodological reflexivity.' (Plows, 2011, p. 4). A few pages on she goes a little further, and makes the case for tilting the frame:

'Especially in sensitive and complex areas such as reproduction and genetics, better forms of participatory democracy are essential to break out of the polarised debate framed in terms of people being "pro or anti" Individual choice or informed consent in specific contexts. It is important to set the debates on some different tracks; to broaden, or to tilt, the frame.' (Plows, 2011, p. 10).

This is a difficult approach to pull off without risking injecting too much of the author's own concerns and preoccupations. Nevertheless, to continue with some

of the points raised in section 1.2, above, on framing, it is certainly also true that in choosing whom we interview, what questions we ask and what issues we find interesting and important, researchers are always in a sense tilting the frame. In my own case one 'tilt' was to take the concerns of natural scientific researchers more on their own terms than do some social science researchers. This was achieved in part by my choice of research questions. In particular the second question (what are the impacts of contemporary governance regimes on natural scientific research?), while secondary in overall importance to the first question within my research, helped to provide a particular focus to investigation of the first question.

To build an understanding of the political context and character of governance, and of the two-way links between STS / SSK themes and governance, I developed, through my analysis of the two case studies, answers to the following question:

What role do important themes in the discourse of contemporary governance, specifically precaution, participation, engagement, pluralism and deliberation, play in its substantive constitution?

In both cases new Acts of Parliament were passed in the past ten years following extensive public and Parliamentary debate. These Acts, to a greater and lesser

extent, updated earlier ones covering each area. In examining and characterising the process of change in governance of tissue and embryology at the legal and regulatory level, three interrelated aspects were examined: the extent to which governance frameworks were substantively altered through the political process; the role of existing governance frameworks within the political debates; and the relationship between the political process, governance frameworks and natural scientific research.

Pertinent to my study, Hammersley and Atkinson warn, on the theme of trying to get 'better' and more truthful accounts: 'this is important, but it can also be problematic: "frankness" may be as much a social accomplishment as "discretion"' (Hammersley and Atkinson, 2007, p.49). The governance of tissue and embryology in the UK emerged out of contentious political debates. Going into and coming out of these debates, participants had aims and aspirations that they attempted to develop in the context of a political landscape that had some unknown but also some known parameters – participants had to feel their way, but they also knew which way things were going to some degree. Similar points apply to other specific debates and more general debates on science governance. Naturally, with varying degrees of calculation, differences between private thoughts and public utterances characterised these debates; in part statements and positions were and are advanced with an eye towards prevailing norms and political realities. This necessitated, at times, challenging the

statements interviewees made through, for example, asking them to comment on the opinions and approaches of others involved in the debates or on materials gained from other data sources. Analysis of the two areas, tissue and embryology, was helpful in this regard in that it allowed a degree of analytical triangulation through the comparisons participants whose focus of work is one case study drew with the other.

I took a grounded theory approach to analysis of the interviews and indeed other research materials, in particular but not exclusively, the approach developed by Strauss and Corbin (1990) rather than that of Glaser, in the sense of his response to the former pair during the 1990s. The approach views social life as a process characterised by conflict and contestation leading to the construction and reconstruction of narratives and political compromises. As Strauss and Corbin put it:

Grounded theory is an action / interaction oriented method of theory building. Whether one is studying individuals, groups, or collections, there is action / interaction, which is directed at managing, handling, carrying out, responding to a phenomenon as it exists in context or under a specific set of perceived conditions. (Strauss and Corbin, 1990, p. 104).

This approach was well suited to analysing aspects of the processes under study, governance and changing governance, which were characterised by such processes of action, interaction, conflict and management of change.

In developing my argument I paid particular attention to the aspect or idea of governance as the channelling of activity by Government, quasi-governmental bodies and regulatory bodies, though I situated this within a context that has become more complex and to a degree more 'bottom up'. Relatedly, I examined the channelling of debate and discussion through governance, and the 'assumption of the authority to categorize publics and identify "proper" ethical positions' (Moore, 2010, p. 204) by governmental bodies.

Broadly speaking, I followed Brownsword (2008) in viewing regulators narrowly but regulation and governance broadly. Somewhat differently from Brownsword and other legally- and philosophically-orientated scholars, I paid more attention to an issue he notes but does little to develop – the political and sociological factors that influence and contextualise the approaches to governance adopted by Government and other agencies involved in governance. In connection with this, Lyall et al make an observation that I found particularly fruitful for my research:

'Salamon (2002a, 37) describes the result of the "paradox of third-party government" where policy-makers seem to be under increasing political

pressures to select those tools of public action that are most difficult to manage and the hardest to keep focused on their primary objectives. Indeed, many of these new tools of governance are horizontal (Ringeling 2002, 588-9) – communication / public information; networking; public-private partnership – and not based on a view of government controlling the actions of others.’ (Lyll, Papaioannou and Smith, 2009, p. 9).

Some STS / SSK writers, radical discourse analysts, critical social theorists and deliberative democracy analysts have theorised, discussed and critiqued the governance of natural science. Some have also engaged directly and indirectly with political and policy debates on the ways in which governance regimes could be changed. Accordingly, this body of work is considered as an input into the public discussion of and as a contribution to the construction of new forms of science governance. Their work is also, in part, considered as an output of the construction of new forms of governance: through engagement with the political and policy process, the issues, ideas and questions addressed by these same theorists have in part been framed by those ongoing processes.

In this PhD, data collection, analysis and interpretation in relationship to governance in the context of case studies played a central role in informing the conclusions to the broader context and questions. But moving from conclusions in the specific cases to broader conclusions required further data and



interpretation. In chapter three I discuss the idea of the changing governance of science directly and in chapter four I introduce the case study chapters (chapters five and six). In doing so I discuss methodological issues relating to the case studies in more detail.

## **1.5 Thesis plan**

### Chapter Two

In this chapter I dig deeper into debates within STS and SSK, outline how key theorists, in particular the more critical ones, conceptualise governance, consider some critical perspectives on STS and SSK, and reflect on the reasons for examining some theoretical approaches more than or rather than others in this thesis. That some strands of social science have taken such a strong interest in critiquing and attempting to change governance of natural science research provides a window into examining and characterising this body of thought. Unlike some philosophically-focused critiques of SSK in particular (e.g., Haack, 2007) I search hard for the political and sociological motivations that drive this body of social science analysis and use this understanding to examine why it is that important strands within SSK see themselves, and perhaps prefers to see themselves, as without power.

SSK has helped to highlight some important issues, such as the meanings and values scientists bring to debates, the way that particular lines of inquiry are opened up and closed down through a focus on scientific aspects of issues and the reification of concrete and specific forms of knowledge in risk debates.

However, radical elements in SSK are very ambitious, utopian to an extent, which has helped to blind them to the influence their ideas, in the hands of others sometimes, have had. The focus on critique, of the real and presumed institutional and cultural power of natural science, adds to this: there is a lack of sympathy, or even interest, in natural scientists' problems; and a lack of interest in the ways in which some natural scientists have absorbed and responded to some social science analysis, even if not always in ways that social scientists anticipated or imagined.

### Chapter Three

In this chapter I look at some aspects of natural science governance that defined the social contract for science after the Second World War. I then focus on some aspects of natural scientists' perceptions of the changes that have taken place in the more recent period and how they have tried to influence and manage change. This discussion includes some preliminary observations on the ways in which the interaction of new and old approaches to governance has combined to shape contemporary governance. In developing this analysis I draw on aspects of STS and SSK as a means to explore governance. Beyond SSK, a novel reading and

combination of Erving Goffman and (more critically) John Rawls is used to interrogate the performative work of natural scientists drawn into public engagement and deliberative exercises during the New Labour years.

Towards the end of the chapter I begin to return to the discussion of critical STS and SSK and consider the analysis of some academic social scientists sympathetic to the concerns of natural scientists. The chapter as a whole and the final sections in particular lays the basis for the following chapter, which introduces the two case studies.

#### Chapter Four

In this chapter I focus more explicitly on how I approached governance and how I used the case studies in the thesis. I discuss different theories of governance. I discuss governance and governance agencies. I discuss how to explore and explain the influence of different ideas and activities on governance. In particular I discuss how to explore the influence of critical STS and SSK in the light of the earlier discussion of the interaction of old and new approaches to Governance. One way I suggest doing this is through a comparative analysis of the Democratic Model with the case of feminist scholarship and politics. The chapter then moves on to a methodological and substantive discussion of how these issues are investigated in this thesis, and concludes with an introduction to the case studies.

### Chapter Five

The first case study: the governance of research using human tissue.

### Chapter Six

The second case study: the governance of research using human embryos.

### Chapter Seven

This chapter reflects on the findings from the case studies and uses these to address the over-arching research question: the changing governance of science. I conclude that New Labour's approach to the governance of science can be considered a hybrid. It was defined by its engagement, rhetorically, performatively and substantively, with the Democratic Model, a model informed by themes linked to SSK and other strands of social science. There were of course many other processes in play. In practice, there was overlap in the Government's and others' treatment of distinct strands, reflecting mixed understandings, pragmatism and disparate aims at Government level. Overall, while there is much continuity between old and new forms of natural science research governance, there have been changes, and some of these changes are the result of the work of various actors, including some STS and SSK theorists, in championing aspects of the Democratic Model.

## Chapter Two: SSK's Challenge to Natural Science Governance

'We may reasonably be asked to cultivate a reflexive self-awareness of the ways in which our scholarly work may play out in the arenas of the "real world". In seeking to explicate the nature of science and the sources of its authority, *all* SSK scholars are necessarily engaged in an enterprise that is as deeply political as it is intellectual, even when their case studies or historical projects seem to be remote from the driving political concerns of late-twentieth-century societies. How could a branch of enquiry that takes as its central preserve the making (and unmaking) of human knowledge be anything but *political* to the core? If nothing else, the recent surge of concern about the "anti-science" tendencies of science studies offers a useful reminder that our field cannot stand detached and apart from debates about the allocation of power and resources to the very institution whose external relations and internal dynamics we seek to illuminate.

In reflecting on the objectives and possible influence of our individual research programmes, we should not be content, however, with an artificially thinned description of the politics to which we contribute. The framework of controversy studies, in particular, with its implied (and I have suggested untenable) dualism between winning and losing beliefs, seems far too constraining to accommodate everything that happens when work in science and technology studies is brought to bear on political ends. We cannot simply be guided by the instrumental uses to which others may put our work, for what we

represent is not merely a “side” in a controversy but an entire worldview: one that is deeply committed to seeing science as a dynamic and integral part of society – a social construct – and to probing its distinctive characteristics with all of the theoretical and methodological resources at our disposal.’

**Sheila Jasanoff, 1996**

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There are some old, classical questions at the intersection between science, politics and democracy. One way in which society addresses them is through governance structures and practices. In turn, the general thinking on governance prevalent at the time, to a greater or lesser degree, will influence the politics and governance of particular areas of research. Human tissue and embryo research are intrinsically connected with the wider trends in the politics and governance of science that have been so widely discussed and debated in the past fifteen to twenty years within the STS / SSK community and more widely. A critical engagement with the debates within and about STS and SSK in this chapter is used to highlight the distinctive approach taken by critical STS and SSK to governance.

## **2.1 Advocating change**

A leading advocate for change is STS / SSK theorist Brian Wynne, who has not only written extensively about a wide range of issues in the field for many years but has also engaged directly and indirectly with government agencies and regulatory bodies. In 2010 he resigned from the Food Standards Agency's Public Dialogue Steering Committee in frustration at what he saw as pre-existing commitments within Government to the development, if at all possible, of Genetically Modified Crops, a commitment that in his opinion undermines genuine dialogue with groups in society. The final straw was FSA chair Jeff Rooker's claim that the public were 'anti-science':

'In being deeply pro-GM in everything but the explicit punch-line itself, this FSA position is effectively a state of institutional denial. This is all the more dogmatically entrenched for its being unrecognised by its own proponents. It is thus either plain dishonest, or it is scandalously unreflective upon, and evading accountability for, its own normatively weighted assumptions. I believe this adds up to a dishonest structural situation, whatever the honesty or otherwise of any individual involved. I also believe that this blind commitment renders even sincerely-meant attempts at public dialogue prone to meaningless public disorientation, abuse, and alienation which undermines public policy authority whichever particular way it might commit itself.'

He went on:

'The issue was never just about what range of framings of the issue, and of different attitudinal positions, would be heard, though this has had to be argued through more than it should have needed. It is also, crucially, about how those wider framings, and those different positions, will be *dialogued with*. I have received no sign that this will even happen, but instead I have been told that policy officials and Ministers will consider them as they please, at their own convenience, with no accountable justifications or explanations or hearing of public and other stakeholder issues and concerns. Thus the "dialogue" is at too much risk of becoming a combination of effective monologue, and extractive research activity. This will only act as yet another public mistrust generator, and all the fine words about taking the public into account in future policy will be meaningless.'

(Wynne, 2010).

Wynne's rationale for being involved was to try to make the process work in the way he wanted it to, or at the very least to hold the government to its own formal commitment to a broader form of engagement and dialogue. He thinks this didn't happen, and more broadly he believes that there have only been limited changes in the governance of science over the past two decades or so; his views



expressed in the resignation letter being of a piece with his assessment that Government is 'Hitting the notes, but missing the music?' (Wynne, 2006).

Many other, a majority most likely, of STS / SSK writers share Wynne's views on these issues to a greater or lesser extent as well as his commitment to trying to effect change, seeing more novelty in form rather than in substance as the talk from Government has moved from public education to restoring public trust to public engagement and dialogue. Pidgeon and Rogers-Hayden (2007), for example, want to use 'upstream' engagement to open up engagement and decision-making around science so that a wide range of perspectives can be brought to bear on early stages of debate on and development of new science and technology:

'the agenda will need to move from industry product based debate (found in downstream dialogue) to broader framing of the issues. This will involve unpacking the assumptions that go into science alongside exploring how technologies fit in with forms of society that citizens wish to have. Thus ideally debating visions all parties have for society and how the technologies can/should/could and cannot be developed to fit within these. This path of deliberating societal visions and assumptions may even lead to exploring some more radical ways of approaching the interaction of citizens and science that have yet to be conceptualized. In the wake of the

GM and BSE affairs in Europe, nanotechnologies may well have arrived at a time where there is genuine opportunity to try something different.'

(Pidgeon and Rogers-Hayden, 2007, pp. 360-1).

At the same time, they fear that upstream engagement could, like previous forms of engagement in their view, serve more to legitimise standard forms of technology decision-making or at least be part of an attempt to legitimise such decision-making:

'it is hard to see how the goals of opening up the research agenda to more public scrutiny on the one hand can be reconciled with a push to use engagement to shape public discourses on the other. On a practical level the danger is that, as with the UK *GM Nation?* Public debate which occurred in 2003 (see Horlick-Jones et al, 2007), engagement will be compromised from the outset by incompatible objectives' (Pidgeon and Rogers-Hayden, 2007, p. 355)

While the work of some STS / SSK scholars is sometimes presented as a defence of public interests against those of industry and government, It is not however just Government, scientists, industry and regulatory bodies that STS / SSK writers are critical of. Some feel distinctly let down by the public. Reflecting on STS / SSK engagement with political and policy processes over the past

decade and more in general, and their own experiences of organising events at which they were both participants and observers studying the processes in particular, Kerr, Cunningham-Burley, and Tutton conclude:

'A form of deferential partnership tends to ensue in these kinds of events, where scientific expertise is supplemented by limited public input... This makes us question the extent to which lay people can ever expose scientific error and hubris, given that the layness we found was so fragile, easily compromised and so readily aligned with expert positions by both scientific experts and others. This seems as true of events that are highly structured as those which are not.' (Kerr, A., Cunningham-Burley, S. and Tutton, R., 2007, p. 408)

Substituting inaction for action, one is reminded of Brecht's *The Solution*

After the uprising of the 17th June  
 The Secretary of the Writers Union  
 Had leaflets distributed in the Stalinallee  
 Stating that the people  
 Had forfeited the confidence of the government  
 And could win it back only  
 By redoubled efforts. Would it not be easier

In that case for the government

To dissolve the people

And elect another?

In the case of STS scholars the typical move in response to the failure of the people is to select another group, or more commonly to enact public participation. But whether it is advocating, arguing or enacting public participation, what, more precisely, are the aims of critical STS and SSK in the arena of science governance, and how have these been pursued through the public policy debates on governance over the past 15 to 20 years in the UK? In the remainder of this chapter I dig deeper into the history of ideas and activity on this subject.

## **2.2 The politics of SSK**

A special issue of the journal *Social Studies of Science* published in 1996 was devoted to 'The Politics of SSK'. A number of different political and theoretical perspectives were on parade, as Brian Wynne put it, and, as he also argued, reflecting on the nature of SSK itself at the start of his contribution, 'the issue of its political relations has never been far from the explicit agenda of SSK.' (Wynne, 1996, p. 357).

Wynne argued that the debate between the explicitly left wing and politically-oriented Brian Martin on the one hand (Martin, 1993) and Harry Collins, representing an SSK focus on issues with limited explicit connection to politics, on the other, was too narrow and dominated by what he termed a 'decisionist' mode of analysis (a critique he was to replay in his response to Collins and Evans' 2002 paper setting out a 'Third Wave' of science studies, which in his view was overly preoccupied with propositional questions).

With caveats, Wynne accepted the central critical points of the reflexive turn advocated by Woolgar, Ashmore and others, but his own interests were more externally oriented: 'I try to exploit the insights of the broad reflexive turn of the 1980s in SSK, but focus *externally*, on the institutional and the political-cultural level.' (Wynne, 1996, p. 359). As Charis Thompson observes, the American Scholar Sheila Jasanoff has a similar approach: 'While most of the studies in SSK and ANT focus on the lab or on relatively discreet episodes of science, Jasanoff has taken STS into the broader political realm by looking at different national styles of accommodating, promoting, and using science for governance.' (Thompson, 2005, p. 50).

It is this external focus on institutional and political-cultural matters that provides the link in their work between methodology and political questions, and provides the basis for their work on the governance of science. As debate within and

outside of STS and SSK has developed since 1996, Wynne and Jasanoff have often teamed up to pursue shared concerns and objectives.

Wynne argued in his paper (Wynne, 1996) that not only was the debate between Martin and Collins concerned with too narrow a set of issues but also that the debate within STS / SSK was framed through this confrontation and that his was a minority view. But if that was true at the time it was not to remain so for long, or, with a nod to Wynne's own concerns, it was not to remain so for long at least at the level of discussion and discourse. By the mid 1990s the terms Left and Right were losing clear meaning in mainstream politics and sociological analysis (Giddens, 1994) and the BSE saga was a catalyst for changes in part in line with the concerns of campaigners and scholars such as Wynne. Ever since the crisis point of 1996, critics of previous Government policy and institutional scientific practice, notably campaigners, some STS / SSK scholars and other writers on science and governance, have successfully influenced the public discussion of a number of issues in politics, governance and science. As discussed in chapter one, three obvious examples are the significance and meaning of the BSE / vCJD issue itself, GM crops and food and, directly relevant to this PhD, research using human tissue in the fall out from the discoveries made regarding retained organs and tissue at Alder Hey hospital.

Some STS / SSK scholars were active participants in the political and policy debates that took place after 1996, at a number of levels – engaging and working with campaigners, writing reports, running public engagement exercises, advising Parliamentary committees and sitting on commissions among other things. This orientation to intervene runs through the writings and intellectual work of such scholars as much as it does their practical activity, and it was something they had prepared for.

*Misunderstanding Science? The public reconstruction of science and technology*, published in 1996, is one example of a deliberate and focused intellectual intervention. In their introduction, the editors, Alan Irwin and Brian Wynne, describe the book as a ‘fresh line of analysis’ (Irwin and Wynne, 1996, p. 12) but also a synthesis, based on two decades of work in the sociology of scientific knowledge, which, they argued, had ‘convincingly demonstrated the *socially negotiated* nature of science’ (Irwin and Wynne, 1996, p. 7).

Clearly, then, fresh for those who hadn’t read the two decades of work; less so for those who had. But this merely highlights the ambition to intervene in and influence debates: ‘the general argument in this book is that we need to rethink and reconceptualise the relationships between “science” and the “public” if we are to make progress at the level of either understanding or practical intervention.’ (Irwin and Wynne, 1996, p. 7). The particular mechanism through

which influence was to be attempted was *policy*; thus was born the policy turn in STS and SSK: 'each of the chapters has implications for *practical interventions* in this area. In the concluding chapter we will address this theme directly – what are the policy implications of the new approach to “public understanding” which has been developed in this collection?' (Irwin and Wynne, 1996, p. 10).

The signalling of intent, the drawing of lessons in each chapter, and the double run at the issues by the editors in an introduction and a conclusion combine to give the book characteristics of a manifesto and a call to arms. The editors also sought to locate their intervention within what they understood to be a changing society: 'We will also attempt to locate the content of this book within the changing structure of contemporary society, and, especially, debates over the nature of modernity and the cultural dimensions of political change.' (Irwin and Wynne, 1996, p. 16). The changes they pointed to were, in some dimensions at least, accelerated by the fallout from the discovery of a link between BSE and vCJD, which was confirmed in the same year the book was published and which soon precipitated intense discussion of how science should be governed.

One broader cultural issue with distinct policy implications they were clear on was that the 'problem' was not so much the public's misunderstanding of science as science's misunderstanding of the public: 'In so far as it can begin to recognise and reflect openly upon its own deep cultural biases, science may find the latent



heat of evaporation of the public understanding problem to be surprisingly low. The politics of legitimation may be best conducted by questioning the anxious culture of control.' (Irwin and Wynne, 1996a, p. 219). Furthermore, science needed to show greater understanding and respect for local knowledges, not simply because this would aid science's understanding of the public, but because these are forms of knowledge on a par with science. Or, put another way, science as commonly understood is itself contextual – 'the context in that case generally being one of *ceteris paribus* assumptions and laboratory controlled conditions.' (Irwin and Wynne, 1996a, p. 220). 'Rather than attempting to maintain a knowledge hierarchy', they went on to argue, 'the aim should be to acknowledge and build upon this broader network of knowledge relations – always accepting that together they can represent a rich and well-tested body of contextual knowledges.' (Irwin and Wynne, 1996a, p. 220). The issue, ultimately, was about 'who should control science' (Irwin and Wynne, 1996a, p. 221).

The themes presented and developed in *Misunderstanding Science?* run through the many articles and reports produced by Wynne and other STS and SSK scholars in the years since 1996; scholars whose broad orientation and aspiration is to open up a space for a constructivist and political interrogation of science and its institutions. While it is perhaps the case that the most widely known studies cover agricultural and environmental issues, the analysis has

been applied to a much wider range of cases. Indeed Wynne argues that the trends he is concerned about affect all areas of science:

'We have meandered blindly from nuclear power in the relatively early post-war years of institutional science advice for policy, through a dense variety of other imbroglios involving scientific knowledge as supposed public policy authority, including thalidomide and other pharmaceuticals, chemical pesticides, food irradiation, chlorofluorocarbons, whooping cough and later MMR triple vaccines, radioactive waste management and disposal, waste incineration, oil and gas rig environmental risk assessment and disposal, BSE, high voltage power lines, and other electromagnetic fields.' (Wynne, 2006, p. 213).

Even medical genetics, widely seen as an area of science and medical practice in which professionals and patients work closely together based on a high level of trust, is not immune to the corrosive influence of institutional scientific arrogance according to Wynne (Wynne, 2006, p. 212).

In the following sections I outline some of the key features of this constructivist and political analysis and approach, in part by contrasting it with others in the field and beyond. There is a difficulty in defining just what constitutes the essence of the approach, and accordingly which scholars are aligned with it. It would be

difficult and perhaps foolish to be too definitive about this. My aim is to point to themes that define a constructivist, political and at times activist tendency in STS and SSK; one with a particular orientation to challenging the influence of institutionally dominant natural science.

### **2.3 Instrumentality and the urge to control**

That there is a relationship between science, decision-making and power is pretty much beyond dispute – only the most apolitical philosopher or scientists could possibly deny it. Coming at the issue from a traditional left wing perspective, the distinguished geneticist Richard Lewontin posed the question and some of the dilemmas it leads to like this:

‘The penetration of science into political and civil society, however, poses a special problem for the operation of the democratic state. On the one hand the behaviour of the state is supposed to reflect the popular will, as determined either by a direct appeal to the opinion of the people or through the intermediary of their elected representatives. On the other hand, the esoteric knowledge and understanding required to make rational decisions in which science and technology are critical factors lie in the possession of a small elite...

...Why would the Salvadorian immigrant woman who cleans my office believe that she and the Alexander Agassiz Research Professor at Harvard have sufficient commonality of interest and world view that she ought to trust my opinion on whether her meagre hourly wage should be taxed to support the Human Genome Project? ...

.... For both questions, what knowledge is worth acquiring and how we are to apply knowledge when we have it, there is a tension between the ideal of democratic decision, the power of which is vested in the “people” and their representatives, and the demand for expert knowledge, the power over which is vested in a small elite. Just as democratic institutions intervene twice, once to decide what is to be studied and then to decide what is to be done with the study, so the elite possesses a double power, first to assert their exclusive competence to acquire knowledge and then to use the authority of that same knowledge to influence social action.’ (Lewontin, 2002).

STS and SSK is a heterogeneous field. While many would agree with some or much of what Lewontin argues in the above quote, there are some distinct aspects to the STS / SSK critique of natural science and natural science governance. In relation to risk issues, for example, whereas some environmentalist campaigners and left wing activists had typically tried to challenge the powerful by presenting concrete truths about harms caused by

particular technological applications, Wynnian SSK stressed rather inherent and deep-seated uncertainty, challenging the powerful's (and indeed everybody's) pretensions to knowledge. The editors of *Late lessons from early warnings* put it like this: 'Complex reality demands better science, characterised by more humility and less hubris, with a focus on "what we don't know" as well as "what we know".' (European Environment Agency, 2001, p. 193).

Underlying this characterisation of knowledge and uncertainty is a broad theoretical difference not only with strands of environmentalist and left wing thought, but all modernist approaches to politics and knowledge. In their introduction to *Risk, Environment & Modernity*, Szerszynski, Lash and Wynne complain about social science's complicity in the modernist project and all that goes with it:

'The translation of things "environmental" into authoritative scientific and policy vocabularies occurs in ways which could be described as, among other things, epistemologically "realist", positivistic, disembedded, technological and cognitivist, and that it thus tends to mask important cultural, social and existential dimensions of the contemporary "environmental crisis".' (Szerszynski, Lash and Wynne, 1996, p. 1).

While superficially the concerns of this strand of SSK might appear to align with the work of sociologists and risk theorists such as Anthony Giddens and Ulrich Beck even if they don't fit with traditional left wing and environmental thinking, in fact the critique takes in these thinkers as well. *Risk, Environment & Modernity* arose out of an international symposium held in 1992 'founded on a critical examination of the perspectives of Ulrich Beck, focusing on modernity, risk and the cultural dimensions of contemporary environmental issues.' (Lash, Szerszynski and Wynne (eds), 1996, p. vii). 'Most of us will argue that Beck has not gone far enough in his break with the dominant "technological paradigm" in environmental analysis' was the verdict of the editors (Szerszynski, Lash and Wynne, 1996, p. 3). The alternative, they argued, is a hermeneutic project, drawing upon critics of Enlightenment rationality such as Ernst Bloch, Theodor Adorno and Max Horkheimer, to expose the meanings mainstream science (both natural and social) imposes on publics and the meanings and cultural resources available to resist this:

'This book constitutes a sort of "slow manifesto" against such tendencies in the social sciences more broadly, presenting a number of different accounts of the environmental phenomenon in late modernity which are in different degrees constructivist rather than realist, hermeneutic rather than positivist, poetic rather than technological, situated rather than disembedded.' (Szerszynski, Lash and Wynne, 1996, p. 2).

Debating Giddens and Beck in another collection of essays, *Reflexive Modernization*, Lash at least hoped that the 'slow manifesto' might gain traction because as he saw it the processes of individualization that they all agreed upon lead to hermeneutics acquiring a central importance in reflexive and other processes. The task of social scientists was to engage with and develop this trend.

In summary, the most general and important theme of the strand of STS and SSK whose core interests are political and institutional is a critique of what it regards as the instrumentalism and urge to control that it believes animates modern science and its leading institutions. Implicitly and at times explicitly this critique contains the projection of an alternative that draws on some strands of anti-modernist, environmental and feminist thinking, which in turn, returning to more modest policy-oriented goals, it is hoped can provide resources to change the practice of science. In *Misunderstanding Science?* Wynne and Irwin put it like this:

'If the social purposes of public knowledge are to uphold less instrumental and exploitative relationships between human society and nature, and between human beings themselves, as much of the impetus of new feminist, environmental, and other social movements and post-modern

critique would claim, what does this imply for the redefinition of “science” as valid public authority?... it is important for scientific institutions to recognise that science is often seen by public groups as a resource for the powerful in society – and against the everyday interests of the weak. Only deliberate – and deliberately humble – efforts in this area can begin to address the issues.’ (Irwin and Wynne, 1996a, pp. 218-220)

From this overarching diagnostic and prognostic framework much else follows, including the particular flavour given to such analytical categories as reductionism, boundary work, how the public is conceived and constructed and how risk issues and promissory discourse are understood.

STS and SSK scholars with this interest and perspective have doggedly attempted to shine a light on these issues and create a space for academic reflection upon it. It is an ongoing struggle as far as many are concerned. Wynne was an advisor to the House of Lords committee that produced the important 2000 report *Science and Society*. Despite explicit rejection of the idea in the report, society is still wedded, believes Wynne, to the original cognitive deficit model as an explanation of public attitudes towards science. This is a kind of alibi for science, he believes, which explains the ‘persistent institutional projection and reinvention’ that occurs around the issue. This excuses what he calls today’s ‘culture of scientism, or institutionalized idolatry of science’, which ‘is bound to



treat public rejection of those things done in the name of science, as rejection of science, because it has already so falsely narrowed its moral imagination to the idea that support for the policy stance is determined by scientific fact, and that no alternative is left.' (Wynne, 2006, p. 214).

The title of the paper from which the above quote is taken, 'Public Engagement as a Means of Restoring Public Trust in Science – Hitting the Notes but Missing the Music?', does a very poor job of capturing the passion and frustration contained in pretty much every paragraph. He concludes by despairing of the ability of those involved to see even the most basic points:

'Scientific institutional actors and the policy officials they advise seem unable to recognize these basic points, as the epistemic culture of instrumentalism and control which defines modern scientific knowledge has been allowed to pervade and latterly to define public science-policy institutional culture.' (Wynne, 2006, p. 220).

The concluding claim, about instrumentalism coming to pervade and latterly define public science-policy institutional culture, points to a perspective on historical developments. And indeed, for Wynne, the need for his particular focus on challenging instrumentalism and control arises not just from its central role in shaping everything else but also from a change in way scientists and their

institutions behave, and the way in which society relates to science. He points to 'a powerful change in science's role since the 1950s, from one which *informs* public policy, to one which also now, by default, *provides public policy with its meanings*', and he believes that social science should focus on this rather than drifting off to examine other questions, such as categorising expertise:

'By this I mean that, first, techno-scientific imaginations of innovations in a widening range of areas of social life, have become the imagined ends of public policy, to create the conditions of innovation for these end-points; and more specifically, when such prospective innovations encounter social questions, almost the only public form of concern, thus public issue, recognized by policy institutions, is that of "risk." This therefore, inadvertently or not, becomes the public meaning by which such issues are defined *as public issues*. I would suggest that social sciences, especially those claiming to deal with publics and science, have a responsibility to challenge this development, rather than to reproduce and reinforce it... That typical members of the public have always and for good reason wished to understand science in terms of its institutional realities, of its forms of ownership, control, driving imaginations, and directions, and not only or even primarily in terms of its technical contents alone, has been recognized in our field for at least sixteen years (Wynne, 1991). These dimensions of "science," and their versions of "the public" including

“public interest” or “public good,” continue to beg for attention.’ (Wynne, 2008, p. 29).

## 2.4 Propositional questions and ‘decisionist’ thinking

The role played by propositional questions or a ‘decisionist’ mode of analysis to use Wynne’s earlier formulation of the issue became the focus of intense debate following the publication of Collins and Evans’ ‘The Third Wave of Science Studies’ in 2002, and then their book *Rethinking Expertise* in 2007. As was the case with earlier discussions, and later ones, as often as not the argument was about what the argument should be about, a familiar theme in STS / SSK controversies in general. For Wynne and Jasanoff, Collins and Evans’ new focus represented, at best, a diversion from the institutional focus they regarded as the priority. The following three quotes give a sense of the issues, contrasting perspectives and confusions:

‘To sum up, we all tend to believe we can make internal judgements of expertise upward, downward and horizontally. The sociology of attribution is the study of the way actors negotiate the right to judge expertise; public legitimacy can be assigned to judgements made in any direction, and those judgements which do in fact gain public legitimacy gain it as an outcome of the interplay of power, alliance-building, and so forth. For example, in recent

years the folk wisdom view has given a great deal of legitimacy to upward judgements while reducing the potency of downward judgements. The normative view that we are developing here is that internal technical judgements, which are of good enough quality to contribute to science and technology policy, can be made only when they run downwards.’ (Collins and Evans, 2007, p. 63).

‘The main point of contention I have with such critics as Collins and Evans (2002, 2003), Kusch (2007), or partial critics such as Kerr (2004; and maybe Durant?), is not as they seem to assume, about the extents of “lay expertise.” It is more fundamentally about what they assume to be the *basis* of public divergences from scientific expert views, when these occur. These are not divergences of propositional knowledge-claim, or anyway, not that alone; but they are divergences of an ontological kind—about meanings, concerns, relationships and forms of life. Whereas these colleagues wish to reduce the public issues to knowledge and thus “expertise” or its lack, I want to insist upon dimensions of contested meanings, and contested concerns (and thus, of what is deemed relevant), and the institutional-scientific denial of legitimate difference here.’ (Wynne, 2008, pp. 22 – 23).

‘We can surely sustain a respect for real expertise, scientific and non-scientific, which remains conditional, for example upon what the issues at

stake, and the aims of knowledge are defined to be, as well as on judging its validity against whatever epistemic criteria are in play. Collins and Evans' form of realism seems to demand unconditional surrender to dominant, often scientific, frames of public meaning. This would also involve abandoning commitment to real practical collective exploration of better human relational possibilities, as woven in with our knowledges. I think it appropriate to maintain a tension between what we might imagine as deeply entrenched and maybe "inevitable" social-cultural realities of modern society, and what (with help from our analytical repertoire) may be worthy of reimagination.' (Wynne, 2003, p. 413).

Wynne is to the point with his insistence on the dependency of argumentation on 'what the issues at stake' are, on the political framing of a number of key issues, and the need to bring to the fore the full variety and range of public meaning rather than framing issues in terms of science. This is especially the case when considering areas in which a number of different forms of knowledge and expertise are brought together, when what is at stake is perhaps disagreement over predictions about future developments based on these different kinds of expertise. Such areas have been termed 'wicked problems' and are far from atypical today. Collins and Evans close off a full engagement with this set of issues in their characterisation of 'Wave Two' and 'Wave Three' of science studies. Or perhaps they provoke but don't follow through: when Collins and

Evans argue that Wave Two solved the problem of legitimacy and now Wave Three must address the problem of extension; it is hard to avoid the conclusion that they think Wave Two also *contributed to* the problem of extension in the way it dealt with the issue of legitimacy; Wynne and Jasanoff certainly respond accordingly.

However, there are a number of debates in which the view one takes on propositional questions, the answer one gives to them, is important for the way one views the wider context in which they are framed. For example, the causative role of HIV in the development of AIDS (Kalichman, 2009) or the relationship between MMR and Autism, a debate in which Collins and Evans (2007), Fitzpatrick (2004) and Offit (2008) effectively demonstrate that some STS / SSK scholars have not exactly covered themselves in glory (for example Irwin, Jones and Stilgoe, 2006).

Further, to acknowledge the political framing of some debates and the importance of exploring public meanings does not of course give carte blanche to SSK writers to engage in this kind of analysis. Nor can it be taken to imply that public meanings are clear-cut or uncontested – careful attention needs to be given to the values social science analysts bring to the table. STS and SSK make much play of the ways in which Government, regulatory agencies, scientists and scientific institutions perform publics through their actions and projections;

attention also needs to be paid to the ways in which critical social scientists perform publics in pursuit of their critique of the institutional power of natural science. This has implications for an understanding of the way in which critical STS and SSK approach case studies, which, as I discuss in the next section, is sometimes closely related to how they handle propositional questions.

## **2.5 Social scientists and social hype**

Charis Thompson succinctly and thoughtfully explains the organic fit between STS and SSK and ethnographic approaches: 'Synthetic, a priori, and purely interpretative methods, for example, are all viewed suspiciously if they are not bolstered by empirical work. Versions of empiricism and positivism, thought of as not requiring any interpretation (as advocated in some natural and social science methodologies), are viewed as equally suspect.' (Thompson, 2005, p. 32).

Accordingly, while one finds much engagement with theory in STS and SSK, as well as periodic bouts of theoretical debate and infighting, a lot of the work and thinking is done through case studies.

But, as discussed above, how case studies and propositional questions should be approached is a contested point. More than this, distinct strands within STS and SSK do not always maintain a consistent approach on the issue: their political commitments and aspirations influence the weight given to empirical

findings on a case-by-case basis, as well as which experts are considered worthy of listening to. The current vogue within the natural scientific community and beyond for emphasising the role of evidence in policy formulation (see, e.g., Henderson, 2012) has created something of a dilemma for social scientists whose sympathies on some issues (such as environmental, anti-big pharma or anti-tobacco industry) are with scientists who are critical of industry. Across a wide range of issues today, ethical and political dimensions are often presented as or subsumed within detailed arguments over evidence of one kind or another (for an excellent study of this process see Kabat, 2008).

A mirror image difficulty for some social scientists is that they find it hard to take a stance on propositional questions when the question is wrapped up with an institutional and political issue they take a critical stance on (see, e.g., the discussion of options for the disposal of the Brent Spar oil platform in Collins and Evans, 2007). Relatedly, social scientists sometimes struggle to achieve a coherent approach to ethical questions that have a similar character to propositional questions and are also wrapped up in an institutional and political issue to which a critical approach is taken.

To illustrate the point, consider feminist scholar Marie Fox's detailed discussion of the hybrid embryo debate (Fox, 2009). She is keen to stress from the outset that she is not adopting an 'anti-science' position:



'In tracking these developments I am not adopting an "anti-science" position, which is how I shall argue opposition tended to be characterized. Rather, I aim simply to chart the emergence of characteristic patterns of reasoning and the success of scientific lobbies in promoting their agenda. I argue that in this process of valorizing science, dissenting voices were marginalized and as a result of these efforts the official government line shifted decisively in favour of the research.' (Fox, 2009, p. 105).

In the conclusion to the article she brings it all together:

'by downplaying the concerns of opponents of such research, space for dissent about these forms of research was effectively closed off and opponents were marginalized. To express objections entailed being depicted in a largely homogenous way as anti-science, probably influenced by irrational religious beliefs and mired in historical debates that had already been decisively lost. Through the deployment of a range of rhetorical strategies – the promotion of faith in science and the law, the representation of "human admixed embryos" as effectively human, their creation as a small incremental step in research procedures which have a long and accepted lineage, and a prohibition on their gestation and birth – space for oppositional arguments was minimized. Moreover, the

government's concern to secure British pre-eminence in embryology research and regenerative medicine was enough to overcome its undoubted misgivings about the ethics and efficacy of the research.' (Fox, 2009, p. 119).

But surely opponents or critics of hybrid embryo research could have seen these strategies coming and done something about them at the time? At the very least they must have tried? The interesting thing is that even after the event Fox finds it hard to do so. Hard, that is, in writing, not hard in the rough and tumble of campaigning. As soon as she starts to consider the arguments made against hybrids, there is some awkwardness in her presentation. She notes that the statutory regulator, the Human Fertilisation and Embryology Authority (HFEA) tried to massage responses and minimize the concern evident in its own consultation by stressing medical benefit, but she doesn't give an account of why it was that the unease one encounters in such surveys was never expressed forcefully in public in a non-religious way. She complains that the Government and scientists characterized the opposition as being motivated by religious impulses; she then notes that the prominent voices in the media and Parliament arguing against hybrids did stress religious arguments, suggesting that this was problematic. But what was to stop someone else putting forward different arguments? She is uncomfortable with the arguments coming from a religious

perspective. But she is also uncomfortable with arguments based on species transgression, the ones that, to a degree, she herself draws on:

'In consequence, oppositional voices tended to be portrayed as emanating from a position that was anti-science and concerned to prevent transgression – whether of nature, species boundaries or appropriate moral limits. Intellectually such claims are hard to sustain, given the difficulties of defending arguments grounded in anything so vague as species integrity or “the natural”'. (Fox, 2009, pp. 115-6)

She then says more about why she doesn't like arguments about species integrity or the natural but then quotes US Conservative bioethicist Leon Kass on repugnance as maybe giving some weight to an argument based on species integrity or the natural. For Kass, such responses signal: '[R]evolts against the excesses of human willfulness, warning us not to transgress what is unspeakably profound. Indeed... repugnance may be the only voice left that speaks up to defend the core of our humanity' (quoted in Fox, 2009, p. 116). She immediately expresses unease again with such arguments but points to something she wants to do: 'While I have no desire to shore up the “central core of our humanity” (whatever that may mean), I do think it may be worth seeking to tease out what lies at the root of the unease about species-mixing.' However, rather than doing the teasing out that she thinks needs doing, she then notes that Melanie Phillips

and Lord Alton made arguments based on repugnance and taboo when they opposed hybrids, before, once again, complaining that these kinds of people advancing the argument served to associate opposition with conservative political and religious voices.

Not only can she not point to or explain why a non-conservative (with a small or large c) couldn't make a secular voice be heard above the religious din, she struggles to make an argument in print herself. In the end the point seems to be that there is popular unease and that this was suppressed, in part by associating it with religious views. In so far as she makes a different argument it is the one about breaking down species barriers or more particularly that interspecies entities would introduce moral confusion into our existing relationships with non-human animals and into our relationships with the entities themselves (citing Scott and Baylis, *Crossing Species Boundaries*, 2003). But of course by this point in the presentation she has already explained why she doesn't really like such arguments.

A common resolution of the tensions caused by handling propositional questions or propositional-like questions contained within an institutional and political issue a theorist is critical of is to contextualise or reinterpret the significance of the propositional question by linking it with other issues or engaging in forms of 'slippery slope' reasoning. Ironically, these forms of social hype argumentation

can often be found in writings that are critical of the promissory discourse of natural scientists.

To maintain the focus on issues relating to embryology while illustrating this, consider the arguments of feminist scholar and writer Donna Dickenson. For Dickenson, stem cell research in general is hype ridden; ‘the promissory technology *par excellence*’. But her commentary on the meanings and implication of the way the science is pursued, supported and constructed, is itself a form of hype:

‘It’s been said that stem cell research encourages a view of the natural world as an artefact: “to see the entire natural world, the human body along with it, as having the status only of material to be manipulated”. By creating immortal stem cell lines touted as having the potential to reverse degradation and decay, we may even see ourselves as remoulding the biological universe. Government science policies have long tended to “privilege the promissory”, and stem cell research technology is the promissory technology *par excellence*.’ (Dickenson, 2009, p. 71).

Or consider Sarah Parry’s reflections on the hybrid embryo debate in particular. In their introduction to *Nature After the Genome*, editors Parry and Dupre argue: ‘In public arenas, much of genomics research is couched in promissory terms –

as a future means to revolutionize medicine, agriculture, ecology and conservation... no doubt most eagerly anticipated are the cures for intractable diseases in humans, constantly advertised as lying just around the corner but frustratingly failing to manifest themselves as practical therapies.' (Parry and Dupre, 2010, p. 4). This is a reasonable implicit criticism. But how different is this kind of natural science promissory discourse from the social hype discourse that Parry engages in later in the same collection (the entities under consideration in this case, lest we forget, are very early stage embryos)?:

'much of the humanist agenda (see Twine, this volume) has involved separating, essentializing and bounding categories of human and non-human animals, and is marked by discourses of human exceptionalism that have all too often served to legitimate certain forms of oppression and exploitation of non-human animals... The creation of interspecies entities for stem cell research involves an unprecedented yet unequal involvement between human and non-human animals. In the very creation of these novel entities, decisions are being made about who lives and who dies.' (Parry, 2010, p. 115-119).

Similar patterns of reasoning and similar patterns of social hype can be found in some social science literature on human tissue research. I discuss this in chapter

five. Through chapters four to seven I discuss the contribution of this kind of critique to contemporary governance.

## 2.6 Reflexivity and institutional analysis

In *Misunderstanding Science?* Irwin and Wynne challenged the way they believe 'the public' has been constructed:

'A "the public is usually implied to be an aggregate of atomised individuals with no social composition, hence no legitimate autonomous cultural substance;...

C it is assumed that the actor's basic values are identical with those of science – for example, that she is concerned to maximise control, rather than perhaps to negotiate and adapt to actors and forces recognised to be beyond such control or which should be beyond such control. Hence, the epistemological commitments which frame science, namely instrumental control, are assumed – wrongly – to be the automatic norm defining all valid knowledge;

D lay people are assumed to desire and expect certainty, and risk-free environments, so that their lack of enthusiasm for science can then be attributed to their alleged inability to face up to science's "grown-up" recognition that risk and uncertainty are intrinsic to everything. Yet our

research reinforces previous work in showing no such naïveté on the part of the public; indeed it shows the central kind of risk being faced as that of dependency upon increasingly expert-imbued social institutions, the basis for trust in which is obscure'. (Irwin and Wynne, 1996a, p. 215)

They went on to argue that:

'It is an important finding from our research that, since public experiences of science can never be detached from imputed institutional interests and agendas of whatever kind, the manifest *lack of reflexivity* on the part of science in public only amplifies any existing tendency for public groups to mistrust it.

It follows from our argument in this book that "useful" scientific knowledge needs to be reflexive and self-aware rather than dismissive of such social and epistemological concerns as irrelevant and "soft". If science is to work with rather than against public groups (or simply be ignored by them), then "usefulness" and "self-reflexivity" must form part of the same social and institutional processes. What is meant by science in given cases must be more open to structured reflection and negotiation, with particular attention to the conditions of validity of the relevant knowledges.' (Irwin and Wynne, 1996a, pp. 215-216)



In his own chapter in the collection, focusing on the Cumbrian sheep farmers, 'Misunderstood misunderstandings' Wynne took these observations a step further, seemingly suggesting that those in a position of power find it hard to be reflexive:

'it is interesting that those who would be regarded as the representatives of traditional society showed this reflexive capability, whilst the representatives of enlightened modernity, namely the scientists, did not (Wynne 1993; Michael 1992). The scientists show no overt ability to reflect upon their own social positioning, that is upon the latent social models which their scientific interventions imposed on the farmers. Perhaps the distribution of reflexive capability (or impulse) is itself a contingent function of social relations of power.' (Wynne, 1996a, p. 43).

An argument he also seemingly made in the *cri de coeur* at the end of his 2006 paper 'Hitting the Notes...': 'Scientific institutional actors and the policy officials they advise seem unable to recognize these basic points, as the epistemic culture of instrumentalism and control which defines modern scientific knowledge has been allowed to pervade and latterly to define public science-policy institutional culture.' (Wynne, 2006, p. 220).

Wynne's apparent position on this question has been subject to a specific and detailed critique by Darrin Durant (Durant, 2008). Durant focuses on what he deduces to be Wynne's key interest and mistake, 'the desire to preserve the autonomy of the lay actor in the face of hegemonic control of meanings by experts.' (Durant, 2008, p. 5). Wynne rejected this analysis in a response (Wynne, 2008), pointing instead to his focus on institutional values and commitments rather than any analysis of the inherent reflexivity or autonomy of particular actors. But if the above quotes are not to be taken in the way Durant takes them, should they instead be taken as rhetorical flourishes on Wynne's part serving a political goal? Or as indicating *the absence* of coherent institutional analysis, or perhaps a cultural theory of institutional character and role is implicit but not developed? My own assessment is that Wynne's focus on the lack of reflexivity of the institutionally powerful and his apparent championing of the reflexivity of lay actors is a part of his theoretical approach, but only a part. As discussed in 2.1 above, critical STS and SSK will often champion lay involvement and lay meaning or appear to do so as a part of its challenge to dominant framings and the power of institutional natural science. But in principle or at root critical STS and SSK is not intrinsically committed to favouring what are commonly called lay meanings over and above expert ones. Nevertheless, Durant is right to point to the analytical tension that arises in political and policy contexts, for in these contexts the emphasis is often very much on challenging natural scientists' framing of debates through championing lay involvement. And

in frustration at a failure or a perceived failure to shift dominant framings, claims have been and are made about institutional power and reflexivity.

## **2.7 Natural scientists as fellow researchers – a lack of empathy**

Wynne, like Jasanoff, has clearly stated that his primary focus and concern is natural science as public authority rather than natural science as a research activity:

‘It is worth also noting that Durant’s otherwise excellent discussion and connection of the reflexivity debate in science studies between for example Bloor and Lynch (and more recently, between Bloor and Latour), with mine in the public encounters with science domain, nevertheless falls foul of just that lack of problematization I opened with, about what we mean by “science” in such domains. The definitive science studies exchanges on this have always been focused on science as research and specialist knowledge-production activities, whereas mine have always been about a very different “science,” namely that being deployed as attempted public authority.’ (Wynne, 2008, pp. 23-24).

This is no doubt true, but from the perspective of natural scientists it might not be such an important distinction. Natural science is a continuum of activity, just as in

its own way social science is. Among other things findings open up and legitimise future research activities, and in turn those research activities lead to findings. It is an ongoing process and it is not a simple task to focus attention simply on science as public authority. Indeed, critical social scientists recognised the connection between natural science as a research activity and natural science as public authority when, concerned that society was being presented with a series of *faits accomplis*, they made the turn to 'Upstream Engagement' in an explicit attempt to shape the research agenda by injecting different values into the process. Put another, and more concrete way, challenging science as public authority is reasonably taken by natural scientists to have consequences for science as a research activity. Was the digging up of GM crops by activists in the UK a challenge to science as public authority or the sabotage of a research programme (the crops were planted as a part of a trial to test certain issues)?

Whether the challenge is made to science as a source of public authority or whether attention is paid to research practice, an influential strand in STS & SSK sees natural science as the object to be critiqued more than it sees natural scientists as fellow researchers struggling to develop knowledge. There is, in short, a lack of empathy and understanding. This runs through into the very framing of some social science analysis and the way in which categories are developed and deployed.

For example, Nicola Marks, writing about stem cell scientists, uses Gieryn's famous paper on 'boundary work' in a suggestive fashion: 'some researchers who work on AS [Adult Stem] cells refuse to argue that a high differentiation potential for these cells is enough to stop work on ES [Embryonic Stem] cells, instead pushing for research on all cells. This line of argument is often taken to "protect the autonomy" of science (Gieryn, 1983: 789-91) and exclude ethical reasons from becoming relevant to the choice of future research directions.' (Marks, 2010, p. 43). There is something of the 'when did you last beat your wife?' about this line of characterisation. Most natural scientists involved in the area don't see much of an, or any ethical problem with working on any kind of cell. As far as they are concerned there aren't many serious ethical issues. And they really do think that pursuing research on different kinds of cells at the same time is the best way to advance knowledge. They are not 'excluding' anybody else from making a different argument.

More generally, one of the issues discussed in the exchanges between Collins and Evans on the one side and Wynne and Jasanoff on the other, was the role and importance of tacit knowledge. For Collins and Evans the tacit knowledge gained through immersion in a community of researchers is essential to proper work in the field, and is an important platform from which to consider the wider significance of findings. This could be extended to saying that researchers, through their practical and day-to-day immersion, have an important insight into

how ethical issues play out in practice and into how governance works, if for no other reason than that they have been brought face-to-face with the issues on a daily basis.

Of course we should be wise to the perspectives professionals might bring to issues and to the possibility of special pleading, but such suspicion shouldn't be the default position. It shouldn't, but to an extent it is for some social science critics. Consider again Kerr, Cunningham-Burley, and Tutton's paper (2007), which discusses a number of debates they had both taken part in and studied:

'The main speakers at the conference, who had academic backgrounds, also conveyed their expertise through a combination of esoteric language and identification as a particular type of expert, often in contrast to another type of expert (e.g. "I am a sociologist, not a scientist"). They also appealed, on many occasions, to dialogue and partnership. For example, at the beginning of [medical geneticist] David Porteous's final speech he commented: "... the first thing I will say is how useful I think this meeting has been and how fortunate, I think, I have been to be able to sit here and listen to all of the comments. I hope this doesn't sound anything other than a measure of that, but I haven't heard anything fundamentally different from what I've heard from other such meetings that we've had in the past, and from things that we've thought about. So, I'm relieved in the sense that all of

the complexities are there, and they all need to be worked through, but I haven't found one yet that really throws a major spanner in the works ..."

Here, the boundary between his technical and ethical knowledge became blurred, but he nevertheless maintained his expert position through his oversight role; a role based on what he presented as a detached appraisal of the discussions in which the other participants engaged. When he implied that the core set of scientists involved had already anticipated the ethical issues raised at the conference and were on the way to working them out, he presented the conference itself as secondary to the research. This seemed to imply that ethical understanding follows from a more privileged form of technical understanding, further underlining David Porteous' and his Generation Scotland colleagues' expertise while maintaining their commitment to public involvement and dialogue more generally. Indeed, such distinctions are already somewhat blurred in the multi-disciplinary context of the Generation Scotland endeavour.' (Kerr, Cunningham-Burley and Tutton, 2007, pp. 404 – 405).

The authors are engaged in various rhetorical strategies themselves. They also say some things that are at face value problematic. The boundary between Porteous' technical and ethical knowledge does not seem blurred at all in the statement he gave. Nor does he appear to claim that he or other scientists have 'anticipated' the ethical issues raised at the conference. Rather, he says that he

has come across the issues in other settings and thought about them. Nor is it clear that he is implying that ethical understanding follows from a more privileged form of technical understanding. The lack of empathy and the intellectual biases to which it gives rise serve to reinforce Robin Williams' warning about the role that STS and SSK may be coming to play:

'The arguments that STS researchers deploy have consequences for different groups—proponents and opponents, scientists and lay publics, industry and policymakers. STS started with a generic commitment to challenging the exclusive role of technical specialists in science and technology policy—and sought to provide a critical account of the powerful industry and state actors that lay behind yesterday's high technology futures. But these historical analytical and political stances may no longer be an adequate guide to the role STS is coming to play in the more complex and dynamic world of today. In the current climate STS may need to give a more balanced attention to the promotion and control of technology, to addressing its benefits as well as its risks, to considering the full range of diverse interests and public pressure groups favouring as well as opposing new technological and medical developments and even perhaps addressing the experiences of scientists and engineers, who may not recognize themselves, their imputed authority and goals in some of the more demonized accounts emerging of the field.' (Williams, 2006, p. 342).



## 2.8 Wynnian SSK's unreflexivity

Sheila Jasanoff, in the quote at the start of this chapter, recognised that SSK might be asked to account for its own role. But Williams' appeal to STS and SSK to do just this; more, to reflect on its own role, has not found a receptive audience in the political, institutionally-focused and activist wing of STS and SSK of which Jasanoff is a prominent member. Whether it be in response to Collins and Evans or in assessments of Government policy in 'Hitting the Notes...', the Wynnian strand of SSK remains fixed on pursuing the critique of both science as public authority and the institutional values of science. It does this in part because it is committed to creating a different politics and culture around science, a different world even. Joyce Tait, who has studied and observed Wynne and others in action over the years, remarks on the agenda-driven character of their work:

'If you look at these cases such as BSE, as being what influenced people to turn against GM crops, the first time I saw that written down was as a question that was raised by Wynne's group when he was running a focus group with members of the public in a project funded by Unilever. I've no way of knowing whether the public raised that issue spontaneously or whether it was suggested. That's the problem with focus groups: they're very, very open to manipulation by people who've got strong opinions

themselves and are using that opportunity to frame the whole issue in the public mind. That really doesn't get challenged very much. I'm not saying you shouldn't do focus groups, but have that in mind, that it's a very powerful way of framing a new technology in the public mind, especially as these focus groups often get an inordinate amount of publicity in the press, far more than their validity should suggest. It's just one small group of people in a room that you don't get to hear – it is recorded but we don't get to hear it...

... They get reinforcement from the academic system. Their approach is seen as academically good social science, so they are reinforced and supported in that way. They're challenging policy and politics. They're not challenging the public because they're manipulating the public I think. They're challenging industry, but they want to do that anyway, and they're not challenging their paymasters in the social science funding council. So there are several wins in it for that kind of approach. I think Brian Wynne's resignation letter. [from the Food Standards Agency's Public Dialogue Steering Committee] gives his perspective on what he was trying to achieve through that particular committee: he was trying to achieve a change in the political system rather than just discuss GM crops.' (Interview, Tait, May 2011).

There is nothing wrong with wanting to change the culture around science or having broader political and cultural ambitions. Many people have such aims and aspirations to one degree or another (in varying directions of course). But the methods by which aims are pursued have consequences for analysis. Oddly, for a strand of analysis that puts such emphasis on reflexivity and the need for reflexivity in those lacking in it, there is something deeply unreflexive about the thinking of the Wynnian strand of SSK. It finds it hard to put itself in the picture, to consider its own influence, to consider the way in which it brings or attempts to bring meanings and interpretations to bear on debates and processes:

‘Since it appears to be so creatively resistant to simple empirical contradiction, it has to be seen as reflecting a deep institutional-cultural need rather than a deliberate deception... it has been cumulatively entrenched over decades and energized by profoundly emotive feelings and insecurities about power and authority... A key feature of this entrenched and, to its practitioners, *unseeable* culture is the way it unwittingly performs its other, namely its publics... until a social agent, collective or individual, is able to place their own “self” into the frame of questioning in interaction with others, it will not be in a position to genuinely hear those others, because it is instead determinedly if inadvertently imposing its own projections of the imagined other into the inauthentic “listening” relationship.’ (Wynne, 2006, pp. 217-219).

Wynne is of course talking about scientists and Government. But many of the same points could be applied to him and some other politically oriented SSK scholars. However, Wynnian SSK has a big point to make in response: it is the institutionally powerful who need to be challenged and who need to change. Wynne and others think it is scientists and government that must adapt. Scholars with this perspective genuinely believe theirs is the most important agenda, one that is as yet largely unfulfilled. They continue to see themselves as underdogs. Despite their success in influencing some discussions, they believe that in terms of substantive governance, little has changed.

## **2.9 STS, SSK and the 'Science Wars'**

In the quote from Jasanoff with which I began this chapter, she observed that 'the recent surge of concern about the "anti-science" tendencies of science studies offers a useful reminder that our field cannot stand detached and apart from debates about the allocation of power and resources to the very institution whose external relations and internal dynamics we seek to illuminate.' She was referring to what has been called the 'Science Wars', and the way in which some if not many natural scientists regard STS and SSK. The Science Wars began around 1994 in the United States when the tensions long evident between many natural scientists and some philosophers on the one side, and some exponents of STS

and SSK on the other, erupted into the open. In that year molecular biologist Paul Gross and mathematician Norman Levitt launched a full-frontal attack on STS in their provocative book *Higher Superstition: The Academic Left and Its Quarrels with Science*. The attempt by STS writer Andrew Ross to mount a counter-attack in 1996 backfired spectacularly when a special issue of the journal he edited, *Social Text*, became a Trojan horse for the natural scientists' camp. Tucked away at the end of a collection of essays designed to show-off the breadth of STS thinking was a paper by New York physicist Alan Sokal: 'Transgressing the Boundaries: towards a transformative hermeneutics of quantum gravity'. Upon publication, Sokal exposed it as a hoax, and a media furore ensued. Sokal quickly teamed up with an old friend and fellow physicist, Jean Bricmont, to pen *Intellectual Impostures*. They challenged postmodernist writers on two counts: for their meaningless use of scientific analogy and terminology, designed to lend a false air of profundity to their theories; and for their relativist epistemology, which leads them to view science as just another human convention, or even myth.

In the UK a minor version of the 'War' erupted around the same time, one of the skirmishes being around the book *Misunderstanding Science?*, following a very dismissive review of it by UK scientist Lewis Wolpert. In the years that followed writers on both sides of the Atlantic attempted to reflect on what the key points were. The heat has gone out of the issue to some degree, but at the same time each side has failed to see much light in the others' arguments. Philosopher

Susan Haack, in *Defending Science – within reason*, and elsewhere, regards SSK as self-defeating (relativism undermines the claims of its proponents as well as the scientists they study) and little short of crazy at times. At best it is just cynical – we've moved, she believes, from Old Deferentialism to the New Cynicism. The craziness angle is the central theme of John Zammito's *A Nice Derangement of Epistemes*, which takes us on a tour of philosophy of science from Quine through Latour to STS and SSK. The derangement as he sees it is radical reflexivity, digging away at the foundations of knowledge until the house falls down. It is all, according to Zammito, 'an instructive *reduction ad absurdum*... The denouement was pure farce: the Sokal affair.' (Zammito, 2004, pp. 232, 234).

The analyses by Haack and Zammito hit home in many regards against some post-modern and social science assertions to have definitively undermined natural science's claim to some truth content. Natural scientists can point to the cumulative character of the findings of their disciplines, the ability of more recent theories and findings to explain both the positive findings and to resolve the difficulties thrown up by previous theories. But the analyses by philosophers such as Haack and historians such as Zammito miss the mark in as much as they take the issues raised by the Sokal affair to be the defining issues for the debate, or for characterising STS and SSK. The more political and institutional issues, including the reflexive methodology used to understand the issues that are of

central concern to many STS and SSK scholars, and that are indeed at the centre of many debates within society today whether understood using the categories of STS and SSK or not, represent a distinct, if at times, but only at times, connected set of issues. It is these social and political and issues that I am concerned with and that I focus on through this thesis, as I analyse the relationships between STS / SSK, governance and natural science research.

### **Chapter Three: The Changing Governance of Science?**

In this chapter I look at some aspects of natural science governance that defined the social contract for science after the Second World War. I then focus on some aspects of natural scientists' perceptions of the changes that have taken place in the more recent period and how they have tried to influence and manage change. This discussion includes some preliminary observations on the ways in which the interaction of new and old approaches to governance has combined to shape contemporary governance. In developing this analysis I draw on aspects of STS, SSK and social science theory as a means to explore governance. Beyond SSK, a novel reading and combination of Erving Goffman and (more critically) John Rawls is used to interrogate the performative work of natural scientists who were drawn into public engagement and deliberative exercises during the New Labour years.

Towards the end of the chapter I begin to return to the discussion of critical STS and SSK by contrasting that analysis with the analysis of some academic social scientists sympathetic to the concerns of natural scientists. The chapter as a whole and the final sections in particular lays the basis for the following chapter, which discusses theories of governance more formally and introduces the two case studies.



### 3.1 Key moments in post-war research governance

Siddhartha Mukherjee's *The Emperor of all Maladies: A Biography of Cancer* richly deserves the critical praise it has garnered. Beautifully and delicately written, but also bold in some of its characterisations, it is, as one reviewer put it, 'that rarest of things – a noble book'. Mukherjee truly rises to the challenge of providing us with a history the subject matters deserves. His is a story of, as he puts it, 'inventiveness, resilience, and perseverance', that is at the same time a story of 'hubris, arrogance, paternalism, misperception, false hope, and hype, all leveraged against an illness that was just three decades ago widely touted as being "curable" within a few years.' (Mukherjee, 2011, p. 7)

While stretching from the Ancient Greeks to the present, concluding on the cautiously hopeful theme of 'The Fruits of Long Endeavors', in many ways the core of the book is the story of the rise and fall of the 'The War on Cancer'. And without it being an explicit theme, Mukherjee's whole book and this central core in particular draws our attention to changes in the governance of science. Among other issues there is the complexity of interactions between goal driven projects and basic research; political and bureaucratic goals clashing with those of science; the rise of public advocates and patient activism; and rising concern about experimental trials on human subjects and scientists' access to patient data without consent.

Very quickly, the 'War' that President Nixon declared on cancer started to fall apart: 'Theories were shattered; drug discoveries stagnated; trials languished; and academic meetings degenerated into all-out brawls... The War on Cancer seemed, at times, to have devolved into a war *within* cancer.' (Mukherjee, 2011, p. 193). While some useful knowledge emerged from it, and while one could try to argue that the, broadly speaking, failure of The War on Cancer provided some lessons, it was also the case that many scientists were sceptical, hostile indeed, about it from the beginning.

James Watson, co-discoverer of the structure of DNA thought it was premature, bound to lead to a waste of huge amounts of money on mediocre science. Cancer scientist Sol Spiegelman compared it to launching the Apollo programme without knowing Newton's laws of gravity. Spiegelman's comparison was a response to the fact that the Apollo programme was the direct inspiration and the model as far as The War on Cancer's advocates were concerned. But it wasn't the only model. The other major historical comparison used in aid of the War on Cancer was the Manhattan Project to build an atomic bomb during World War Two. For Spiegelman and others however, this comparison merely brought out how President Nixon and the supporters of the War on Cancer were changing the governance of science.

I began this thesis with Robert Oppenheimer, 'father' of the atomic bomb, and Vannevar Bush, head of the US Office of Scientific Research and Development during World War Two. Oppenheimer argued that 'it is not possible to be a scientist unless you believe that knowledge of the world, and the power which this gives, is a thing which is of intrinsic value to humanity', while Bush, in his famous report *Science, The Endless Frontier*, envisaged endless benefits to American society from scientific advance.

As I went on to discuss, society today has a more ambivalent attitude towards scientific advance. Beginning in the late 1960s, society has also come to reject or at least question the approach to science governance advocated by Oppenheimer and Bush. The War on Cancer was one clear and stark example of this. Mukherjee captures some of the dimensions of this well:

'As Bush perceived it, even the widely lauded Manhattan Project epitomized the virtues of basic inquiry. True, the bomb was the product of Yankee "mechanical ingenuity." But that mechanical ingenuity stood on the shoulders of scientific discoveries about the fundamental nature of the atom and the energy locked inside it – research performed, notably, with no driving mandate to produce anything resembling the atomic bomb... So Bush had pushed for a radically inverted model of scientific development,

in which researchers were allowed full autonomy over their explorations and open-ended inquiry was prioritized...

... The plan had a deep and lasting influence in Washington. The National Science Foundation (NSF), founded in 1950, was explicitly created to encourage scientific autonomy.' (Mukherjee, 2011, p. 121).

It was just this autonomy and the model of governance of which it was a part that Nixon challenged, and that others have challenged in different ways ever since.

Of course it would be naïve to take claims about autonomy and pure disinterested research at face value, or at the very least to interpret them simply.

There has always been a social contract for science; the issue is shifting emphasis within the governance of science rather than the imposition of an entirely novel system of control. But nevertheless, the historical shifts that Mukherjee highlights are real and important. STS scholar Mark B. Brown puts it like this in considering the social contract for science in the United States post-World War Two, what has changed, and how it would be very hard to undo the changes:

'The government provided money, with no strings attached, and science produced knowledge, technology, and medicine. The social contract was always a fragile construction, and the separation between science and

politics was never as complete as nostalgic critics of politicized science now claim... Nevertheless, until at least the early 1980s, two basic premises governed U.S. science policy: the scientific community is capable of regulating itself; and if it is allowed to regulate itself, science will produce technological benefits for society. Although the social contract for science continues to dominate popular views of science, it is being challenged by the politicization of science policy, science advice, and scientific research itself...

... Whether their chosen culprit is postmodern constructivism or the Bush administration, critics of politicized science usually call for restoring a presumed Golden Age of “the pure virtue of the pursuit of knowledge.” Such efforts ignore the enormous social forces contributing to the politicization of science, which make it both impossible and irresponsible for scientists to isolate themselves from politics.’ (Brown, 2009, pp. 9-17).

Charis Thompson, another STS scholar we met in chapter two, also agrees with the standard characterisation of the Post War social contract: ‘The idea that scientific research should be autonomous has deep roots in post-war U.S. culture and lay behind the ultimately victorious Program for Postwar Scientific Research developed by Vannevar Bush.’ (Thompson, 2005, p. 223). But she also introduces some caveats and nuances, including the need to take account of the rise to prominence of biology over physics when considering change:

'twentieth-century physics and twenty-first century biology are very different sciences in terms of how (and how directly) they implicate citizens, influence (and are influenced by) statecraft, and produce knowledge... The physical sciences and their objects (like elementary particles) are tremendously needy, especially of real estate, computing power, and the formalities of and probabilities of advanced mathematics. But these are very different demands and rights than those asked for by and owed to the organic objects of biomedical and life science. In biomedicine, people, their personal and collective identities, their bodies and their body parts are materially and custodially involved and implicated in the science. The autonomy of science continues to be an ideal that informs research protocols and professional organizations, but it does not spell out the relations between biomedical sciences and the government or the public.' (Thompson, 2005, pp. 245-266).

Analysing and characterising changing governance implicitly and explicitly relies upon characterising governance itself and developing causal explanations of change. How important are the nuances regarding the post war governance framework? Is Thompson right to suggest that the shift from physics to biology is important? Is she also putting this forward as a causal explanation of change; if she is, what does Mukherjee's history of cancer research governance tell us

about this issue by way of a counter-history? Delving into these three issues – governance, change and causality – can be attempted over longer and shorter time frames, it can be attempted in broad outline and in detail, and it can be pursued across one or several specific domains.

On account of the huge growth in state funding for science perhaps, on account also of the development of explicit ideas about science governance in this period, and, as Mukherjee, Brown and Thompson illustrate in different ways, on account of the fact that many natural science researchers look back (with rose tinted glasses or otherwise) on the comparative advantages of the post war social contract, contemporary changes in natural science research governance are commonly situated in a historical time frame stretching from the Second World War to the present. This often serves as a longer period in which to contextualise changes over shorter time frames, typically the late '60s to the present, and the late '80s / early '90s to the present.

That natural science research governance in the UK and elsewhere has changed since the late 1980s, and that this in turn is in part a development of changes that began in the 1970s and 1980s, is widely agreed upon in some quarters. Within some parts of the natural science community in particular there is a widespread sense that not only has there been change but that some, or much of, that change is problematic for research activity. The issue for researchers is not just

specific pieces of legislation, but the whole context for research activity. To begin to develop the analysis, in the next few sections I shift focus to this end of the spectrum: from the longer time frame and the broad picture to a more recent period, focusing on governance and the approach of scientists to this.

### **3.2 Debating and disagreeing about governance**

The differences in analysis between critical STS and SSK on the one hand and many natural scientists and others that I discuss in this chapter on the other reflect to some extent different starting points: how the nature and merits of governance at the beginning of the period discussed in this thesis are viewed. The differences in analysis also reflect the ambitions for and the desired direction of change in governance: Andy Stirling's comment about social appraisal, that 'of course social appraisal is also reflexively coconstituted – and its outcomes conditioned – by preexisting and encompassing commitments' (Stirling, 2008, p. 266), applies to SSK scholars' theoretical and practical work just as it does to natural scientists', Government's and others'. And in part differences in analysis may also have been influenced by the fact that some STS / SSK writers have been drawn into a relationship with Government and natural scientists which they may not feel entirely or even at all comfortable with, for political as well as academic reasons. At the very least this latter point may have some bearing on the at times over-heated character of the debate.



A particular issue within this debate and disagreement between critical STS / SSK scholars and others is contrasting perspectives on how particular themes relating to governance have been developed, have been used and have guided the work of regulatory and Government agencies. Perhaps some critics of previous governance regimes under-estimate change because regulators and Government have taken ideas and approaches developed by social scientists, and have been influenced by these approaches, in directions that disappoint or frustrate those social scientists. From other perspectives, such as those of natural science researchers, in some contexts the changes are, nevertheless, significant, in a direction that doesn't always accord with what researchers want, and certainly not within a governance framework that contains a notion of the 'freedom of research'. Researchers in the areas covered by this thesis, human tissue and human embryology, acknowledge that Government was formally and subjectively in favour of science in general and sometimes in particular. At the same time they pointed to a whole range of legislative, regulatory and policy initiatives that display little knowledge of the realities of research practice, that cumulatively add up to a new and problematic pattern of governance and that often contain perspectives that scientists regard with suspicion if not hostility.

In assessing the role of ideas associated with STS / SSK theorists in governance the important point to look at is what the ideas 'do' when they become a part of

debate and a part of processes. One issue I examine through the case studies is how the ideas have in practice contributed, perversely perhaps for some of those most committed to them, to channelling and closing down debate, and to reinforcing untoward trends in research governance (untoward from some perspectives), such as centralisation, a premature demand for 'relevance' and bureaucratic management of specialist and professional activity.

So while Andy Stirling argues that 'although instrumental imperatives may as readily be pursued by marginalised groups as incumbent interests, it is by definition the latter that exercise the predominant influence on technology choice' (Stirling, 2008, pp. 269-270), it does not follow from this that campaigning groups (and STS / SSK scholars, if he suggesting a marginalised role for them) have no influence. Further, and more importantly, it does not follow that what he calls incumbent interests are all pulling in the same direction. In particular we need to consider the way in which Government and regulatory agencies are using some of the themes associated with new approaches to governance in their own ways. To open up a discussion of these issues in the next two sections I begin by unpacking, somewhat descriptively, relations within the 'incumbent interests' about which Stirling writes.

### **3.3 Simply the best?**

Science Minister Ian Pearson, in a speech given in 2007, outlined areas where he thought things had gone relatively well from the Government's perspective, and areas where he thought they had gone less well. In the former category he included human embryo and stem cell research:

'To date we have a chequered record on engagement. Difficult issues like nuclear energy and genetic modification have not been handled well. But there have also been successes - our approach to engaging the public in the development of stem cell research in the UK has allowed this country to lead the world. The dialogue on nanoscience has generally been positive. We have all learned lessons. Public engagement is becoming recognised as a valuable part of policy-making. Indeed, one of Gordon Brown's first acts as our new Prime Minister was to encourage the use of citizens' juries.' (Pearson, 2007).

It is not clear from the above quote just what made engagement around stem cell research a success from the Government's perspective, but it is clear that they do regard the governance of stem cell research and embryology more generally as a success story. And it is not just politicians that make this case. The regulator makes the same point. Ruth Deech, former Chair of the HFEA, argues that:

From this period [2001] the UK has led the world in both advancing and monitoring stem cell research. The basis on which it does so is that established by the HFEA in 1991 for the regulation of IVF and embryo storage. (Deech and Smajdor, 2007, p. 28).

In public announcements prominent scientists will also typically praise the UK system of governance: President of the Royal Society, Martin Rees, for example, did so during his 2010 Reith Lectures. What is more, scientists are widely seen to have played a role in developing the governance framework. Some commentators go further, suggesting that scientists anticipated and welcomed it. In an article on the award of the 2010 Nobel Prize in Physiology or Medicine to IVF pioneer Robert Edwards, *Nature's* Alison Abbott concluded by claiming that Edwards 'was equally prescient on the need for oversight of his powerful technique, advocating in 1971 that a legal authority should be established to control IVF. The UK Human Fertilisation and Embryology Authority [HFEA] was founded 20 years later.' (Abbot, 2010).

This presentation of a public consensus between Government, regulator and scientists, about the present and the past, bears some critical scrutiny. In reality, some of the key claims are vigorously contested, and the 'incumbent interests' are far from united. Consider first Pearson's and Deech's bold claim that the UK leads the world in this area of research on account of its approach to governance.

During the joint House of Commons and House of Lords Scrutiny Committee discussions in 2007 of the Bill that would in time be modified to become the Human Fertilisation and Embryology Bill 2008, Committee member (Lord) Professor Winston challenged the Government view: 'America has an unregulated scientific community and yet it is producing by far the most effective and most published and most respected papers in stem cell biology in the world, even though of course it has a President [George Bush Jnr, at the time] who is set against it.' (Joint Committee on the Human Tissue and Embryos (Draft) Bill, 2007, p. 66). Others concur with his assessment on the relationship between the UK system and innovation. Researcher Austin Smith is very forthright:

'I can't see any credible basis for claiming that the UK is in any kind of leading position in human embryo research in terms of the science... in practical terms it's not easy to do in the UK, and we've lost out because of that actually compared with other countries... It's not even just the private sector in the US, it's just non-NIH funded, so there's Howard Hughes and JDRF and many others. There are other European countries like Belgium and Sweden where they have good quality IVF clinics with a reasonable level of research going on. In the UK it really hasn't happened. That may be to do with broader issues than the regulatory framework. It may be to do with the way that IVF is funded in this country and the separation of

clinical treatment from research, which is an issue throughout the NHS. But the idea of the HFEA having a role in the UK supposedly leading the world in stem cell research is farcical... the HFEA reasonably enough wants to bang its own drum and politicians like to have something to bang their drum about. They still seem to be obsessed by the idea that somehow we're ahead of the US because of the Federal ban on funding. Any idiot could just look at the amount of funding from other sources going into this area in the US, the number of researchers, any metric you want to use – it's clear.' (Interview, Smith, July 2008).

Implicit if not explicit within the arguments of Winston and Smith is a very critical assessment of UK regulation and governance. They are not alone in taking such a critical stance, and nor is such criticism a recent thing. Indeed, contrary to Abbott's brief history stressing ethical consensus in this area, the reality is far less consensual. As Michael Mulkay tells the story, in the 1980s, a number of individual scientists, many eminent in the field, as well as some scientific institutions and journals at an editorial level, opposed the framework outlined by Mary Warnock and her Commission, the framework that would later be transposed into law. Robert Edwards responded in this way at the time: 'I deny the argument that [the] scientific impetus will necessarily lead to silly experiments. It would be unwise to jeopardise future advances by short-term recourse to the criminal law.' Another prominent researcher thought that 'the first

part of the report is practical and sensible because it was based on at least 10 years of experience [with IVF]. When you come to the regulation of research it draws on science fiction and so is tinged with hysteria.' (Mulkay, 1997, p. 21).

But, continues Mulkay, when scientists saw the way the political wind was blowing they fell in behind Warnock in the hope and expectation that regulation of research would provide some political protection for their work. As one MP put it: 'the Medical Research Council recanted and threw its full weight behind Warnock.' (Mulkay, 1997, p. 27).

Mulkay's discussion of the process gives the impression of a *volte-face*, and implies a compliment about scientists' tactical sense. But if it is a compliment, it is one that embryo researcher Martin Johnson suspects may be a backhanded one. Johnson, an active participant in the debates of the 1980s, resists the idea that it was primarily an instrumental move by scientists. Yes, scientists did scheme, he agrees, but substantially what they did was to throw the decision open to society and lay out the options – out of this they expected regulations to emerge:

'I don't think we tried to push the research argument, we just pointed out what had happened as a result of research and the consequences of banning further research. I don't think we were dishonest at all in that.'

(Interview, Johnson, July 2008).

Indeed, going further back in time, this is how Johnson believes Edwards approached the issue in the 1970s, and how he believes most scientists approach the issue today:

'He didn't resist regulation, you don't see him out there resisting regulation, he wanted to have the debate in society, he was trying to get society to discuss this rationally for years before it did, until Louise Brown was born, and then it [society] did because it could suddenly see there was something to discuss and so on... the majority of scientists and doctors are perfectly happy to be regulated as long as it's done reasonably, and they can see that there is a genuine public concern. I think apart from the odd one or two they are broadly of the view that as long as regulation is done intelligently and in an informed way with widespread debate, then it's perfectly fine. You may kick against it, you may get irritated by it and you may criticise it, but all of that is legitimate, because it is never going to be perfect and you have to be articulating your concerns.' (Interview, Johnson, July 2008).

Perhaps not surprisingly, former chair of the HFEA Ruth Deech is more sympathetic to Mulkay's (implied) argument. In what reads like a direct rejoinder to Johnson she argues that in a key paper Johnson refers to (Edwards and



Sharpe, 1971) 'Edwards was perhaps committed to the facilitation of science rather than to the imposition of restraints based on public concerns.' (Deech and Smajdor, 2007, p. 29). She develops this point, generalising to broader medical and scientific opinion:

'His [Edwards'] ambivalent attitude towards regulation was revealed when he later described state interference in reproductive medicine as 'Nazism and Stalinism'. If nothing else, this illustrates the way scientific and medical support for regulation fluctuates in relation to what the scientists may regard as the imperative for freedom in research.' (Deech and Smajdor, 2007, p. 29).

This discussion and dispute between Mulkay, Johnson and Deech tells us something interesting and useful about the approach of scientists to the regulatory process and the governance framework, in addition to their concerns and frustrations. Scientists as a group aren't instinctive political radicals any more than anyone else. A distinction needs to be made between their personal views, the views they express in public even, and the extent to which they are inclined or willing to really pursue such ideas in the political sphere. In large part the main concern of many is, in Smith's words, to 'do the bloody experiment'. Freedom to research would be nice. Clear rules are a second best, but under political realities often the most important thing. Johnson's view is too rosy and reasonable

sounding, but he is right to say that scientists rarely reject regulation as a matter of principle. Rather, more typically, they resent the implied criticism involved in the idea of specific regulation while also holding out the hope for an idealised, smooth and efficient system of regulation.

### **3.4 Horror and complexity: human tissue research governance in the UK**

In the arena of human tissue governance, there is less of a formal alliance never mind a substantive alliance, between the 'incumbent interests'. When Secretary of State for Health Alan Milburn read the report into the organ retention practices at Alder Hey Children's Hospital in Liverpool over a weekend at the end of January 2001, he is said to have found it one of the most shocking things or the most shocking thing he had ever read (accounts vary, but either way, an astounding statement). His reaction and the speech he gave to Parliament on the issue the following week in which he described the issue as the worst disaster ever to hit the NHS set the tone for the public discussion of the issue over the next few years. In these years consultation documents and reports were produced, Commissions set up, legislation was drafted and passed by Parliament (The Human Tissue Act 2004) and an authority was established, the Human Tissue Authority (HTA), tasked with licensing some activities and driving through cultural change.

The language used in the Alder Hey report perturbed the medical and medical research community. For Dewar and Boddington the framing of the debate was a case of 'the power of horror over logic'. The tradition of the macabre, they argued, includes two particularly powerful myths: 'The first myth is based on the image of the mad and bad scientist and the second on the fantasy of residual feeling of human sentience in the dead, or parts of the dead. There is evidence that the Alder Hey report has (consciously or not) drawn upon this horror tradition.' (Dewar & Boddington, 2004, p. 463, p. 464). More generally the medical and medical research community was perturbed by the way in which, as they saw it, the Alder Hey report approached the issue as a whole from the point of view of particular families who felt they had been wronged. Without, that is, taking account of professionals' own interests and priorities or the views of patients and the wider public who were less concerned. As Dixon-Woods et al highlight, a number of disease specific patient support groups or groups of families who donate to particular research projects do not view the issue in the way we might imagine 'the public' thinks from the reports of the time and media coverage (Dixon-Woods, Wilson, Jackson, Cavers and Pritchard-Jones, 2008).

It is no exaggeration to say that the research community was also cowed by the response to the report, a response in which researchers were cast as the villains: 'the organ retention scandal was exceptionally powerful in its designation of villains, victims, heroes, and in its organization of the "proper" response to events

and actions, in particular by polarizing the interests of the medical/scientific community and the lay community.' (Seale, Cavers and Dixon-Woods, 2006, p. 38). One aspect of the professional response, or at least of the institutional professional response, was an adaptation to the dominant framing of the issue. Dewar and Boddington noted for example that an editorial in *The Lancet* argued that any material not being used with dignity for a scientific or educational purpose should be 'disposed of in an acceptable way, not left to languish unattended.' How, they asked, 'can anything that is not sentient languish? And what defines dignity in a pathology slide?' (Dewar & Boddington, 2004, p. 464). Pathologists felt particularly demonised. According to Burton & Wells they also suffered from the adaptation of their representatives, which in this case they saw as nothing short of capitulation: 'Histopathologists the length and breadth of the UK have been left bewildered and drained, feeling that there has been a capitulation of professional representation in the face of hostile parents and a tabloid press baying for blood.' (Burton & Wells, 2001, p. 820).

While it was of course the case that Government, like everyone else, was responding to events, the reality is that Government also played a key role in shaping the media response, and it was and is well aware that different groups of patients or different 'publics' had different views. It chose to highlight and respond to particular views, particular concerns, and it chose at the same time to amplify those views. Against this background the Department of Health quite consciously

set about crafting a form of governance in part in keeping with ideas associated with the Democratic Model or new modes of governance, covering not only issues directly relevant to Alder Hey but also a wider set. Hugh Whittall, the lead civil servant on the issue at the time, noted in interview that this was unusual:

‘What I think was really interesting was the opportunity that was taken to take a much wider look at the whole area of regulation and legislation relating to human tissue and human bodies. That was in a sense quite unusual. First, because the natural tendency of Government and the civil service is to do as little as is necessary in any particular set of circumstances. And the second is that the prospect of being able to get Parliamentary time to introduce or revise legislation without there being a critical necessity for it was really unusual, you just wouldn’t expect to do that. So that was the context: the crisis moment of Alder Hey combined with a really, I think probably quite appropriate, decision to use that to look much more widely.’ (Interview, Whittall, May 2010).

It was and is the opinion of Government and many who supported changes to governance of human tissue research that the new values and the new governance arrangements would facilitate rather than hinder research. On its website, the regulator, the Human Tissue Authority (HTA), states: ‘The HTA licenses organisations that store human tissue for research. One of our key aims

is to ensure that research continues to thrive in the UK. We believe that good regulation supports good science, which in turn leads to improved healthcare.'

The relationship between the different trends in governance and the practice of research in this area is a complicated one. I address it in some detail in chapters four and five. But safe to say for the moment that not many researchers agree with the HTA's assessment of the state of research in the UK and its implied claims about the governance framework, be it the law, the regulator, or the combination of both and other factors.

Scientists and scientific organisations anticipated that there would be problems at the time the new framework was being developed. Cancer Research UK for example argued that 'the licensing regime is excessive, unnecessary and disproportionate... its scope and impact has been severely underestimated.' More recently, a 2009 survey of researchers by onCore UK found that 78% assessed the environment as either strict or very strict, with only 19% considering it about right. 92% considered the complexity of the regulatory environment for pathology research as either complex or very complex. Appendix 3 of the published report contains a wide selection of comments sent in by researchers. They are very strongly critical, with many researchers confessing to feeling quite demoralised. It is all a far remove from the HTA's picture of research thriving in the UK. (onCore UK, 2009).

Of course one has to interpret such survey results carefully. Those who are critical might be more likely to respond to surveys, and one other important point to note, one I discuss in chapter five, is that researchers working in large institutions, perhaps in an organised biobank, are more positive about the governance framework than those working elsewhere. Nevertheless, the material contained in the report is consistent with my own findings, including my interviews with researchers more sympathetic to the HTA as well as those who are openly critical. Strikingly, the HTA conducted its own survey of researchers in 2009 and came up with similar results to those contained in the onCore UK report.

### **3.5 Institutional science's political approach and body language**

The recent debates and changes to governance occurred under the three New Labour Governments that ran consecutively from 1997 to 2010. It was a lively period for debates on science and science governance; one marked by a number of initiatives and structural experiments. And indeed a scientific issue, or an issue with a large scientific component, arguably played a role in consolidating New Labour's challenge to the Conservative Government in its final years: New Labour was first elected to power shortly after the BSE scandal came to a head. In the last year of the Conservative Government New Labour used the issue to

illustrate the incompetence of the incumbent regime and also its deference to producer interests over and above consumer interests. Over the first term of the New Labour Government a number of other issues, principally GM crops and foods, the health risks posed by mobile phones and the use of children's organs and other tissue in research were major public incidents which played a role in shaping the official approach to the Governance of science as it became codified in a number of Governmental and non-Governmental documents.

In this section and the next one I build on the description of tensions within and between the incumbent interests illustrated in the previous two sections and begin to characterise some aspects of contemporary science governance, in particular how natural scientists perceive the issues, the problems they face, and how they have tried to handle them.

A key report, *Science and Society*, published in 2000 by the House of Lords Select Committee on Science and Technology, called for greater understanding of public values and a serious dialogue with the public. Not in order to restrict science, but to help it: 'our call for increased and integrated dialogue with the public is intended to *secure* science's "licence to practise", not to *restrict* it.' This report codified official thinking at the time and guided future practice. But there was more than official policy in relation to science policy in play in guiding the



construction and practice of governance. The general patterns of Governmental approach and behaviour were also important.

Simon Denegri has, apart from a brief spell abroad, spent the past twenty years working in the patient and medical research charity sector in the UK. Among other things he was Chief Executive of the Association of Medical Research Charities from 2006 to 2011; he's chair of INVOLVE, the national advisory group for the promotion and support of public involvement in research funded by the National Institute for Health Research (NIHR) and he's an active blogger (<http://simondenegri.com>). He comes to the debates with an instinctive sympathy and enthusiasm for medical research but at the same time a suspicion of medical and natural scientific special pleading.

In spite of or perhaps because of the latter point, he has a fine grasp of the problems facing researchers, medical researchers in particular, and how these problems fit into some ideas associated with defining aspects of New Labour's approach to governance. His reflections on the past fifteen years in particular bring out some aspects and consequences of the restlessness, the search for new domains and issues, that Moran (2003) identifies as defining the 'British regulatory state' following the collapse 'oligarchic club rule' in the 1980s. Denegri points to the political settlement that New Labour crafted, one that accorded a

very important role for science, backed up with substantial and ring-fenced funding:

'for the first time you had a Government that came onto the block that was very serious about putting science at the heart of what it was trying to do: innovation, growth, all those kinds of thing. And it had a very strong lead in Sainsbury who was there a long, long time. When you have a situation in which you have two constituencies who don't necessarily think the same things [Government and science] you need a very strong leader to bring it all together, and I think Sainsbury was that leader. He showed fundamentally very positive and strong leadership, both within Government but also within science. I think we've struggled a little bit since, because we haven't had such a strong leader. But I think that whole thrust from 1997 onwards to put in place a ten-year framework for science, to build NIHR in the health arena, to emphasise translational science, I think all this was a very important creation of that settlement between the two... I think there is a change afoot at the moment, but there is a settlement that you can trace back to 1997 and that period was a period of extraordinary positivity for science: having that framework in place; having that sort of drive; that sort of ambition; that sort of leadership.' (Interview, Denegri, April 2011).

However, while believing that they are prone to exaggerating problems, Denegri agrees to an extent with those scientists who argue that alongside this fundamental commitment to science New Labour was terribly neurotic about governance in this area as elsewhere, which created a paradoxical situation:

‘It’s a bit like, pretend the Government was a horse trainer, training an amazing stallion, but it keeps putting on its own handicap, increasing the handicap all the time. I think there is a paradox there and I think it has happened. There are lots of underlying reasons you could go into. I think the last Government was very neurotic about all sorts of things. It was highly consultative. It was quite passive aggressive when it came to regulation.’ (Interview, Denegri, April 2011).

An aspect of this neuroticism was New Labour’s enthusiasm for and approach to public consultation, which Denegri colourfully characterises as ‘digging up the flowers to see if they’re growing’:

‘Where the engagement agenda has become very, very fuzzy I think is where it’s moved more – and the Government’s got itself into difficulty here – to the James Joyce sort of thing, surveys, opinion polls, which is a bit like children digging up the flowers to see if they’re growing type things, which is disruptive, not helpful. It’s weathervane politics; it just doesn’t help

at all. I have been pretty dismayed actually about the way the Government has approached things like science and society, general public engagement about science. It doesn't know what it wants to do and it doesn't know how to do it.' (Interview, Denegri, April 2011).

Scientific research is, to state the obvious, the archetypical activity of scientists. Research is practically and symbolically what scientists do. Governance regimes for science and scientists often focus on this, as do political and policy debates. In the fall out from the BSE / vCJD issue, scientists might have expected to gain some credit for their research into prion diseases, for monitoring the development of vCJD and for proposing a connection to BSE. However, in addition to New Labour's neuroticism, scientists had to contend with a sceptical cultural climate that included the notion that in some sense scientific arrogance was a part of the problem. As Jonathan Porritt put it, already quoted in chapter one, linking arrogance to a number of other issues, notably, for the purposes of my study, precaution and participation: 'science should be more precautionary; more participative; less arrogant; less compromised by its paymasters; more compassionate and more holistic.' (Porritt, 2000, p. 33). In a review of Porritt's book, natural scientist Lewis Wolpert was characteristically typically scathing:

'This book is an example of anti-science by someone who has little understanding of science but who appears to be happy to use it when it

suits his political purpose... There is also the delicious irony that when science gives Porritt a result he likes, as in the case of global warming, then suddenly there is a change in tone and a switch to “we know that...” who is this new “we”?’ ‘No wonder Prince Charles is so poorly advised. Pity, too, the poor environment that so badly needs rational analysis, hard science and positive action – not moral masturbation.’ (Wolpert, 2000).

With the backlash against GM fresh in their minds, there is much evidence that many scientists took a very dim view of Government activity and shared Wolpert’s disdain if not contempt for Porritt and other critics: in a survey of UK plant scientists, more than 80% believed that the anti-GM campaign had contributed to a general anti-science feeling. Colin Lazarus based at Bristol University stated: ‘the government tends to put popularity at the top of its agenda and has done little to support the rational case for GM. It seemed to start out in support but did not have the courage to maintain its convictions in the face of hostility.’ (Farrar, 2000a). Catherine Hughes reported, based on a Wellcome-funded MORI poll conducted around the same time, that: ‘scientists clearly feel that the public has an erroneous view of their profession, and that they and their work are misunderstood. A further distance between them might be evident in that scientists feel the public trusts a source which they themselves have little faith in – the media.’ (Hughes, 2001, p. 8).

However, not wanting explicitly to engage in lobbying or values-led campaigns, for this would be to step outside their preferred role as insiders in policy and politics, leaders of the natural science community typically engage in a kind of dance or performance regarding the new modes of science governance and Government policy. Accordingly, not all scientists were as critical as well known individuals such as Lewis Wolpert, and of those that were not all thought it politic to voice their criticism so strongly and so publicly. Whatever the mixture of belief and calculation, leading scientists and scientific institutions decided on a more emollient approach in order to try to manage the situation (and in the process eased Wolpert out of his role as a semi-official representative of 'the scientific community'). These scientists stood by their science and worked out a way to try to keep what they saw as untoward arguments and social movements at bay, but without explicitly confronting some of the values involved. In a context in which they were expected to engage with various publics in a more deferential way than they were accustomed to this seemed the obvious route to take in order to secure that 'licence to practise' highlighted by the House of Lords.

### **3.6 UK medical researchers' perspectives on the past 15 years**

The approaches taken by leading scientists and scientific institutions discussed above can be theorised by reference to two seminal sociological and political theorists, Erving Goffman and John Rawls. This allows us to contextualise and

interpret some of the novel aspects of institutional medical scientific activity since the mid 1990s as well as to think about the different levels or layers of perspectives on the changes that have occurred, particularly as expressed and presented in the public and policy domain.

Erving Goffman developed an analysis of the structures of social encounters from the perspective of the dramatic performance. The word person, he observes, in its first meaning, is a mask. Robert Park, Goffman observes in his book *The Presentation of Self in Everyday Life*, argues that “everyone is always and everywhere, more or less consciously, playing a role... it is in these roles that we know each other; it is in these roles that we know ourselves.” (quoted in Goffman, 1990 [1959], p. 30). Goffman was concerned first and foremost with the structures of social interaction that develop when people are in immediate physical proximity to each other. In such circumstances there is a combined effort at impression management; the key point being to maintain a joint definition of the situation:

‘Together the participants contribute to a single over-all definition of the situation which involves not so much a real agreement as to what exists but rather a real agreement as to whose claims concerning what issues will be temporarily honoured. Real agreement will also exist concerning

the desirability of avoiding an open conflict of definitions of the situation.'

(Goffman, 1990 [1959], p. 21).

Of course, people do maintain a distinction between front stage and back stage roles, and relatedly they do seek to change the definition of the situation. In order to maintain the front stage role this is often done cautiously:

'This is sometimes known a "putting out feelers" and involves guarded disclosures and hinted demands. By means of statements that are carefully ambiguous or that have a secret meaning to the initiate, a performer is able to discover, without dropping his defensive stand, whether or not it is safe to dispense with the current definition of the situation.' (Goffman, 1990 [1959], p. 188).

Goffman develops the analysis and tackles a number of wider issues in his magnum opus *Frame Analysis*. In a typically lyrical passage he develops a view on the kinds of human nature that are shaped by such close social interactions:

'The human nature that fits with this view of viewing does so in part because its possessors have learned to comport themselves so as to render this analysis true of them. Indeed, in countless ways and ceaselessly, social life takes up and freezes into itself the understandings



we have of it. (And since my analysis of frames admittedly merges with the one that subjects themselves employ, mine, in that degree, must function as another supportive fantasy).' (Goffman, 1975, p. 563).

In this work as with his earlier book he once again emphasised that he was concerned with close social interaction rather than the organisation of society. However, as he also acknowledged, and as the passage on human nature suggests, his theory points to a relationship between the two. Natural scientists involved in public engagement and deliberation exercises, and natural scientific institutions engaged in the production of reports, might be viewed as performers in Goffman's terms, existing somewhere between intimate personal interaction and the broader organisation of society. They take part in the construction of the definition of the situation, they seek to change it at times, but they are also bound by it in a fundamental sense.

The philosopher and political theorist John Rawls, in his work *Political Liberalism*, argued for a form of public reason based on an overlapping consensus between different doctrines. The idea of an overlapping consensus is moral, he argued, in its object and motivation, rendering the consensus stable over the distribution of doctrines: 'this gives stability for the right reasons, and this distinguishes the idea of such a consensus from a *modus vivendi*.' (Rawls, 2005, p. xli). In this sense (his rejection of a *modus vivendi*), and in his focus on public reason, Rawls'

theory is quite distinct from Goffman's. However, if we take the view that Rawls' approach is both unrealistic in its pure form, but also a real feature of contemporary life – an influence on how politics is conceived, how it is thought it should work, and in consequence how it does work to some extent – then some strong connections between the two ideas, Goffman's and Rawls', emerge.

Rawls argued that faced with a standoff between comprehensive and incompatible doctrines, people could not insist that their own doctrine must prevail. Instead, they should rather seek, or vote for, something else: 'From the point of view of public reason citizens should simply vote for the ordering of political values they sincerely think the most reasonable. Otherwise we fail to exercise political power in ways that satisfy the criterion of reciprocity.' (Rawls, 2005, p. liii). He links his idea to a view on the kind of human psychology that needs to prevail or that he wants to bring about – his body of work, he says, also considers 'how citizens need to be conceived to construct those more reasonable conceptions, and what their moral psychology has to be to support a reasonably just political society over time.' (Rawls, 2005, p. lx).

A (for Rawls desirable) by-product of this is that, to the extent that it works, slowly but surely those outside a consensus become or can be pressured into becoming more moderate. Once again, as with the real world application or consideration of Goffman's thinking, this can lead to the construction of a consensus with real

power. A corollary is that engagement with a consensus can lead to tensions within a body of thought, or fracture a movement.

With the above analysis in mind, one reading of official, that is institutional-scientific, statements and approaches, is that they are sometimes an implicit, perhaps even explicit, rebuke to the more forceful statements of some of the rank and file. The statements are attempts at impression management and are influenced by pressures to conform to a consensus. However, it is also the case that official statements and approaches echo those rank and file concerns.

*A new pathway for the regulation and governance of health research* is an important report produced for and published by the UK's The Academy of Medical Sciences in early 2011. The dominant theme is the problem of complexity, which it summarised in this way:

'Many argue that the complexity of the current landscape, combined with an over-emphasis on privacy and autonomy, has created a conservative culture around access to data which does not always best serve the needs of research or, more importantly, the needs of patients within the NHS.'

(The Academy of Medical Sciences, 2011, p. 61).

The AMS urged the Government to take action to tackle the barriers to effective research. But what the report balked at accepting (or stating) was that Governments in recent years might have neglected the concerns of scientists, or, heaven forbid, have known about the concerns but ignored them. For the AMS, complexity resulted from the accumulation of individual regulatory requirements, each well-intended:

'The complexity of the current regulatory and governance environment has developed cumulatively. New regulatory requirements and checks have been introduced over time to improve on previous arrangements, in response to individual cases of actual and alleged clinical malpractice, or as a consequence of legislation. Each new requirement was well-intended but the combined effect has been the layering of new bodies or checks onto existing functions. A key aim of this report is to consider the regulation and governance pathway as a whole and its net impact on patients, the public and UK health research.' (The Academy of Medical Sciences, 2011, p. 18).

The report did discuss what it called 'cultural issues', but the main emphasis as ever with reports from the institutionalised great and the good was on streamlining processes rather than tackling the public and governmental political issues that lie behind the problem. They didn't even want to acknowledge

elements of deliberate intent of the most basic kind in the Human Tissue Act (about which I outline in detail in the next two chapters):

‘Respondents highlighted the broad scope and application of the Human Tissue Act to materials such as urine, faeces and saliva as the main barrier to research involving human tissue... There was a strong belief among those we consulted that the current situation unnecessarily increases costs and bureaucracy and was not the intention of the Act, which was introduced to prevent the inappropriate retention of body parts and whole organs, i.e. any repeat of events similar to those at Alder Hey.’  
(The Academy of Medical Sciences, 2011, p. 73).

It is unclear the extent to which genuine confusion plays a part and how much is political calculation. But it seems clear that some of the latter must have been involved. As is the norm, it is stated that patient and public engagement with research will improve governance, without, as is also the norm, any discussion of what this might mean and whether indeed some forms of such involvement might lie behind complexity in the first place.

Without, hopefully, stretching the military comparison too far, it is instructive to compare the AMS report with points put forward by retired head of the Medical Research Council, Colin Blakemore, in discussion of the report. Just as retired

Generals have taken to the airwaves in recent years to criticise Government policy in blunter terms than their serving colleagues, leaving the no doubt intended and probably correct impression that they are revealing an opinion widely held within the armed forces, so, writing in *The Times* in advance of publication of the report, Blakemore pointed to the scope of regulations and wondered about the values that reinforced the current situation in blunter terms than the AMS itself:

‘There are regulations governing research on animals, human tissue and embryos; the use of new medicines; the design, governance and conduct of clinical trials; access to medical records; exposure to radiation and the archiving and protection of data. Anyone who puts a finger on another human being in the interests of research faces application forms the size of telephone directories for ethical approval.

A novice in this legal minefield could be excused for thinking that society considers medical research a threat rather than potential salvation from disease....

... all this regulation comes at a huge cost. In fees for the licenses, in time and in research that doesn't get done because so many well-intentioned scientists surrender in the battle against bureaucracy...

... A big problem is the dubious ethical assumption that regulation must protect us indiscriminately against the tiniest risk, the most unlikely

offence and infringement of the least probable individual objection. Of course, we must protect against abuse, but we don't need the current quicksand of regulations to prevent horrors such as Dr Mengele or the Tuskegee Syphilis Study.' (Blakemore, 2011).

While critical of medical researchers in their conclusion, on-the-ground researcher dissatisfaction is noted, and in fact taken seriously by Mary Dixon-Woods and Richard Ashcroft, who point to perceived changes since the mid 1990s in this way:

'The last decade has seen huge growth in researcher dissatisfaction with the burdens and reach of regulation and governance of health-related research. In the UK, researchers find the regulations to be overly burdensome in proportion to the risks of research, costly, intrusive, and an obstruction to the training of a generation of scientists. The perceived negative impact of research governance requirements on the conduct of low risk research in the public interest has been especially heavily criticised.' (Dixon-Woods and Ashcroft, 2008, p. 381).

### 3.7 Some analyses of STS, SSK and change

The survey results and discussion in the preceding sections suggests that the perspective of some natural science researchers and other analysts is that governance has changed and in ways that have negatively impacted on research practice. Some social scientists, typically ones sympathetic to some of the concerns of natural science researchers, link these changes to new approaches to governance characteristic of the Democratic Model. Writing of one of the more recent ideas in the area, Joyce Tait considered it 'surprising that upstream engagement has been accepted so uncritically by the scientific community, given the lack of equivalent scrutiny of the assumptions, values and visions of those who have demanded it.' (Tait, 2009, p. S19). She went on to situate the appeal of the approach in a longer historical context, drawing some other STS / SSK scholars into her argument as she did, briskly rejecting the notion that it has democratic credentials, and worrying about the impact of the approach:

'The tension between scientific endeavour, which is seen as the basis for human progress, and contrary opinions ranging from mild reservation to entrenched opposition, will continue, and upstream engagement is one of its latest manifestations.

If engagement is to satisfy the demands of its proponents who want evidence that its outcomes are influencing decisions, and at the same time



these proponents are influencing engagement in a manner that is critical of the scientific agenda, restriction of some scientific projects is inevitable. As Collins implies, the social science agenda within which upstream engagement is located can be seen as taking us deeper into a mire where we will have no solid evidence base for making decisions about scientific developments (Collins, 2009). Decisions will vary depending on public-opinion shifts in response to the latest events, amplified or modulated by media campaigns...

...as the influence of activists has increased, the role of industry and other professional groups has declined, and the voice of ordinary citizens is still not being heard. Neither situation is satisfactory and the claim that these new approaches to decision-making are more democratic is not being borne-out... There will always be differences of opinion, and upstream engagement seems likely merely to substitute one set of dominant opinions for another set that is no more universal and, if anything, is less based on scientific evidence than the previous one.' (Tait, 2009, pp. S20-S21).

In interview, Tait was in little doubt that change had taken place and that, in the case of GM at least, critical STS and SSK had played a role, albeit indirectly: 'The impact that it's had is that it's been invoked for a lot of actions that have been taken. For example, not using GM crops: that's the area where I can see the

precautionary principle as being damaging in the long run.' (Interview, Tait, May 2011). In thinking about causality, Tait's point that the idea was 'invoked' is of course important. For Tait, the influence of social science academics, in particular those who championed the Democratic Model, on changes in governance is indirect, through an influence on politicians; politicians who are however strongly and independently committed to the change:

'I think there has been quite a lot of change. I don't think they've necessarily influenced it. I think it's come from the political system as much as anything: through voting; through who gets voted into power. I think the fact that the Green parliamentary groups began to have a big influence in Europe on politics had a big impact on the way Governments listened to publics and who they listened to, and the fact that they began to do things as a result. So I think what you've seen is a shift to a much more bottom up approach to policy. As Catherine Lyall talks about in her writing, we've moved to a more stakeholder-oriented style of governance rather than top-down government, bringing public debate into the process of making policy decisions. I think there's been a very strong move in that direction. I think the green groups were influenced by social scientists. I don't think any one social scientist has had a huge impact, but social science has been influential.' (Interview, Tait, May 2011).

Relatedly, rather than taking the BSE / vCJD episode at face value, as self-evidently a 'disaster' driving and illustrating the need for change, some analysts point to a number of sociological and political factors as being significant in the increased influence of new governance mechanisms, including: exhaustion of the Conservative administration by the early to mid-1990s, and to an extent the very idea of effective Government; the rise to prominence of campaigning consumer organisations; individuation within society; an existing predisposition to food scares; and the beginnings of widespread anti-corporatist sentiment. All these taken together led many people and writers to invest unrealistic hopes and fears in science. Then, against this background, New Labour came to power, on the look out for creating some kind of authority within society through making connections with such sentiments (Forbes, 2004; Packer, 2006; Alaszewski and Burgess, 2007).

Burgess, one of the analysts who has made such arguments, draws on Moran's work and points to a fundamental shift in Government's approach to governance, a shift that frames Government's actions and perhaps to an extent those of its collaborators and critics. His focus is on risk governance, but it has a wider relevance, and suggests some ways in which to think about the kinds of interactions involved in the construction of contemporary engagement processes and governance structures:

'Following the BSE crisis, the new government was especially sensitive to "the need to stay in touch with public opinion on new food sciences and technologies" and this drove the GMO and mobile debates (POST 2000, 20). More substantially, Moran (2003) identifies the emergence of a "British regulatory state" following the collapse of what he terms oligarchic "club rule" in the 1980s. A vacuum has been left by its collapse characterised by a restless "hyper innovation" and search for new institutions and ideas through which to engage and govern society. Moran identifies a state and political class compulsively attracted to new domains and issues, in the process extending influence and even control. It may be fruitful to consider the attraction of a trend such as risk campaigning in the context of the confused, post-political world that emerged from the collapse of traditional governance in the 1980s. Under such circumstances it may seem unsurprising that risk campaigning's relative dynamism and apparent public engagement seemed irresistible irrespective of problematic longer term implications.' (Burgess, 2010, p. 71).

### **3.8 Conclusion: working together – to what end and with what effect?**

Launching a £1m project designed 'to make science more accountable', Sir Aaron Klug, President of the Royal Society at the time, made this argument in 2000: 'Science is necessarily run by scientists, but it is ultimately society that

allows science to go ahead and we need to make sure that it goes on doing so. So we need input from non-experts to make sure we are aware of the boundaries to our “license to practice” and, conversely, we need good channels of communication if we want to extend those boundaries.’ (*Times Higher Education Supplement*, 1 December 2000).

This encapsulates a primary aim of scientists, and also their pragmatic approach to engagement and dialogue. There are some timeless aspects to this, but how the relationship works in practice if not conceptually is heavily influenced by the political and governance context of the time. Science Minister Ian Pearson, whose speech celebrating the success of stem cell research I quoted from earlier in this chapter, also talked about the importance of science to the British economy, he talked about his enthusiasm for science, and he talked about his desire to engage with society to discuss difficult and controversial topics. Later in the speech he outlined his idea for a vision for science, and invited discussion of it:

‘Today I want to take the process of refreshing our science and society strategy a stage further by launching a debate around what our vision should be and how collectively we can up our game. What I want to do now is to enlist your help in looking at the Government’s role and the focus of our activities with a view to developing a strategy that reflects the efforts of all in the community. As a starting point, I offer my initial thoughts on a vision of

what we should be trying to achieve, that is: *A Society that is excited about science, values its importance to our economic and social well-being, feels confident in its use, and supports a representative, well-qualified scientific workforce.*' (Pearson, 2007).

Pearson proposed to pursue engagement and dialogue in a number of ways, one of which, the headline in fact, was through the Beacons for Public Engagement Project. And here we run into an apparent ambiguity at the heart of the Government's actions in this area over the past fifteen years. The values and the vision Pearson advanced are at least formally at odds with the conception many others have of what public engagement should involve. More than that, if we look at who was practically involved in this project we find a number of collaborators across the country, some or many of whom most definitely do not share the vision Pearson outlined: in the North East for example it was coordinated by an academic / activist, Tom Wakeford, who is highly critical of the approach of Government and who has had a number of run ins with Government and the 'Scientific Establishment', in particular the Royal Society. This raises the questions: what are the points of connection between Government and the 'Scientific Establishment' on the one side, and the range of academics and activists working on governance and engagement? When they work together, what is the common ground? Why do they work together and what comes out of it? These are the questions to be explored in the next chapter.

## Chapter Four: Governance, the case studies and research design

In chapter one I stated that governance is a broad topic, and that it might be appropriate to use different conceptualisations in different contexts. I quoted Andy Stirling advocating for the following broad approach when focusing on opening up debates:

'The starting point for this analysis is a distinction between parallel, interlinked, and mutually coconstituting processes of commitment and appraisal in technology governance. Here, "governance" is taken to encompass the diverse totality of actors, discourses, structures, and processes implicated in guiding and shaping technological configurations (Kooiman 1993). In these terms, appraisal is about *informing*, and commitment is about *forming* tangible social choices in the governance of science and technology.' (Stirling, 2008, p. 265).

However, it is also the case that governance is, unsurprisingly, both a *broad* and a *contested* category. While there is a good deal of agreement that significant changes have occurred since the 1980s in particular, exactly how those changes should be conceptualised is keenly debated. And these debates do not hinge simply on which theory is most appropriate for which circumstances, but also which theory or approach best captures the main dynamics of governance at a

particular point in time and of change over time. These debates are connected to deep and long running disputes about the connection between governance and philosophical and political theory (Bevir and Krupicka, 2011). This chapter unpacks these debates a bit further in different ways, for example through a comparative analysis of the Democratic Model with the case of feminist scholarship and politics. It moves on to a methodological and substantive discussion of how these issues are investigated in this thesis, and concludes with an introduction to the case studies.

Most writers are agreed that networks and a diverse range of actors play a bigger role today than they did in the past. At one level the debate is about what weight, significance and consequence to give to this analytically, from a, broadly speaking, sociological perspective, and what weight should be given to this from a normative perspective. For Lyall et al, as also discussed in chapter one, the state still plays a significant role, and what's more it should do:

'In this and many of the chapters that follow, we consider some of the "new tools of governance" and how they might apply to the life science industries. We shall suggest that there are actually limits to the all pervasive notion of "governance" and that, instead, the multifaceted policy and regulatory situation that applies to genomics and the life sciences more generally actually argues for the existence of a government-



governance continuum with different aspects of genomics technologies sitting at different points on this spectrum. Despite the political (and academic) rhetoric about new governance approaches, we perceive the enduring capacity of the state (in the North at least) to control and also to frame debates about new technology – hence “the limits to governance”.’ (Lyll, Papaioannou and Smith, 2009, p. 3).

In analysing the case studies and indeed in analysing the whole topic of the changing governance of science, rather than approaches that tend to highlight the role of networks and other social actors and deny or minimise the role of the state, I cleave towards Peters’ argument that ‘State actors and social actors interact to produce governance.’ (Peters, 2011, p. 468), which places me closer to Lyall et al rather than theorists who put a strong emphasis on networks and social movements. The governance of natural science in general and of human embryo and tissue research in the UK in particular, is still relatively ‘top down’, guided by a specific and detailed legal frameworks and powerful regulators.

However, and herein lies a complication and a novelty, not only do we have to consider the interaction of the state with networks and social movements, we must also consider the fact that Government itself and the regulators, formally at least, embraced and promoted horizontal tools of governance – communication and public information; networking; public-private partnership, deliberative

elements – and downplayed ideas of governance that are based on a view of government controlling the actions of others (see Lyall, Papaioannou and Smith, 2009, for a general discussion). This created some novel and, for natural scientists, not entirely positive, outcomes. Relatedly, the battle to influence law making and policy-making, and the outcome, were also shaped by chaotic elements in UK science governance following the BSE episode of 1996. This included attempts to make connections with campaigners through a highly consultative approach to policy-making.

In the next two sections I discuss conceptual issues that bear upon the question of state and regulatory policy, the values pursued through this and how to think about the influence of critical ideas upon it, in particular ideas associated with the Democratic Model. After that I outline the methodological strategy I employed and how in particular I used case studies to further the analysis.

#### **4.1 Governance and governance agencies**

In his *Rights, Regulation, and the Technological Revolution* the legal scholar Roger Brownsword examines how the utilitarian, the rights and the dignitarian perspectives use and regard key concepts, especially consent, harm and precaution (Brownsword, 2008). Given the tensions between these perspectives, he comes to the view that a consensus is not possible, which in turn points to a

fundamental limit to law's ability to govern through command and control measures in areas beset by such fundamental disagreements, a point which applies, he believes, to procedural as well as substantive approaches to governance:

'Although this high theory of proceduralism comes with an impeccable pedigree, it seems a pretty unlikely story. Granted, the diagnosis is sound: for, in a context of pluralism, the problems of stability and authority are most acute when the law takes sides on opposed moral positions; and it is in just these circumstances that a legitimacy crisis is prompted. However, the proceduralist response (as the earlier Rawls might have expressed it) puts too great a strain on the parties. Quite simply, if the protagonists and pluralists are to bargain their way to a solution, where the only force is the Habermassian force of the better argument, then something very fundamental has to give. What the proceduralists ask of the disputants is not that they should give an inch or two but nothing less than that they should abandon their deepest (but incompatible) moral convictions – that is, those very beliefs that are the source of the instability, and which, if insisted upon, would fatally obstruct a consensual accommodation of all reasonable viewpoints, or of principles that could not reasonably be rejected.' (Brownsword, 2008, p. 129)

So what does happen in practice? As Barnes and Dupre succinctly observe, often we do not form a Rawlsian consensus based or not based on Habermassian dialogue. Rather, often we find ways to work around each other (Barnes and Dupre, 2008, p. 238). These are important observations and good as far as they go, but just how do people work around each other, what values are promoted in this way when a societal position is arrived at to one degree or another and embodied in regulation and governance, and what role do regulatory and governance agencies play in this?

In his classic text *The Sociological Imagination* C. Wright-Mills argued that 'Unless they justify institutions and motivate persons to enact institutional roles, "the values" of a society, however important in various private milieux, are historically and sociologically irrelevant.' (Mills, 1970, p. 47). In both case studies Government, civil servants, lawmakers and regulators played an important role. This required analysis of lawmaking, and related to that reflection on how to think about the role of law. In *An Introduction to Law and Regulation: Text Materials*, Bronwen Morgan and Karen Yeung outline a broad approach to the subject of law and regulation: 'We understand "regulation" scholarship as a broad and open-ended category that can readily apply to many forms of intellectual inquiry concerning the purposive shaping of social behaviour, particularly state and non-state standard-setting, monitoring and behaviour modification processes.' (Morgan and Yeung, 2007, p. xiv). The selections in the text are grouped in the

first instance around a distinction between public and private interest theories. It is assumed, they say, by its proponents that is, that public interest theories are optimistic about regulation protecting the public interest, so it is not always considered necessary to examine this empirically (Morgan and Yeung, 2007, p. 43).

Private interest theorists, in comparison, are interested in criticising how public interest approaches work in practice: 'In political versions of private interest theory, political outcomes, and the regulatory rules in which they are embedded, are the aggregate result of different groups pursuing their own versions of the public interest without any overall umpire imposing constraints on the content of those versions.' (Morgan and Yeung, 2007, p. 44).

A neglected issue, by both kinds of theorists, or one that at the very least does not fall easily into one of the two categories, public and private, is the values and aims held and pursued by the regulators and other governance agencies themselves (the umpires). Regulators will typically have their own aims and play a role in shaping the debate that is not captured by either naïve theories of public interest or the aggregating idea of private interests theorists.

Of course regulators and other governance agencies will often claim to be following a general or a particular public interest model when they do play a role.

But how this should be analysed is not straightforward. Stephen Croley argues that 'private interest theories tend to give causal accounts of the emergence of regulatory regimes while public interest theories are more prescriptive, highlighting the regulatory goals that the law should ideally facilitate.' (Quoted in Morgan and Yeung, 2007, p. 52). That public interest theorists have this notion allows or makes it tempting to conflate (confuse themselves about?) the way in which the law is working with the way it should be working. In other words, allows or tempts the analyst into paying insufficient attention to causal explanations that include the role of governance agencies, because they are focused on normative analysis. There may of course also be a performative aspect to this. Acting as if enacting normative principles and discussing issues in such terms allows the pursuit of real world goals (with varying degrees of intention) that may at best amount to a particular twist on those principles and at worst something else.

## **4.2 Analysing influence**

One intriguing aspect of contemporary science governance discourse is the state's apparent endorsement of critical approaches. As we saw in chapter one, the idea that this discourse might imply more, that it might suggest the substantive influence of critical ideas, is one that SSK theorist Brian Wynne finds perplexing and disturbing – he is shocked that anyone could think this: 'My most striking personal experience of STS engagement in policy worlds has been sheer

disorientation at my failure to recognize my own ideas in what has been celebrated as my work's public influence.' (Wynne, 2007, p. 501).

In chapters two and three I suggested that the failure to recognise influence might be found in the nature of radical STS and SSK more than anything else. To develop this point and to think about how to analyse the influence of STS ideas, whether pursued by STS theorists themselves or by others, a fruitful comparison is with feminist thinking and lobbying around government policy and the associated issue of 'governance feminism', about which some academic work has been done.

There are many parallels between feminist and Democratic Model (including STS / SSK) approaches, and an overlapping set of issues have arisen in after-the-event reflections on attempts to influence Government agendas. Consider one particular recent study of feminism by Helen Reece spanning the past two decades in particular. In her discussion of feminist analyses of United Kingdom legislative discourse on stalking 1996-7, Reece argues that feminists underestimated their influence on the debate and the legislation, and discusses why this matters. She scrutinises in particular the work of two feminist scholars who have analysed the stalking debate, Liz Kelly and Catherine Humphreys:

'Kelly and Humphreys believe that feminist research and analysis have had some influence on past debates. But the extent to which interpretations of stalking rode roughshod over feminist analysis reveals to them the fragility of feminist influence on public policy, and conversely the fragility of the feminist hold on public policy explains why a feminist interpretation of stalking did not prevail:

"Feminists have long sought to name the domestic nature... of gender violence, and after almost three decades many assumed that this particular battle had been won. However, the fragility of this shift is demonstrated by the rapidity with which the 'stranger danger' discourse has been reasserted... Within this particular political and socially conservative milieu, feminist discourses can be speedily overridden."

For them, the debate preceding the PHA [Prevention from Harassment Act] illustrates that "even the most simple and basic issues which feminists have placed on political and policy agendas can be displaced" (Reece, 2011, p. 209).

Upon examination, Reece found the claims to a lack of influence on the Parliamentary discourse to be unsustainable. So much so, that 'it is hard to glean the evidence that Kelly and Humphreys are relying on in their critique of official discourse. The lack of empirical data leads me to wonder whether their approach



is postulatory, which would render their interpretation less perplexing.’ (Reece, 2011, p. 220). However, the reality of resonances between feminist analysis and official discourses raises a further set of issues at the same time as resolving some others:

‘There are (at least) two distinct ways to read any such resonances. On the one hand, they can be seen as evidence of feminist influence over or capture of policy-making; on the other hand, they can be regarded as indicating (no more than?) the appropriation of feminist language. As we will shortly see, any attempt to adjudicate here is bedevilled by the difficulty of determining the meaning of feminism, that is, which and whose views count as feminist.’ (Reece, 2011, p. 223).

While scholars such as Joel Best and Janet Halley argue for the first broad way to understand resonances – evidence of feminist influence over or capture of policy-making – Lisa Gotell among others argues for the appropriation explanation:

‘[Gotell] argues that while “the women’s movement can take credit for constructing a discourse that has raised consciousness of men’s “violence against women” as a political problem”, this process involved “many reinscriptions of feminist discourses”, so that “government recognition of

“violence” has been marked by the appropriation and transformation of feminist discourses”. In other words, feminist claims were “subsumed within and used to legitimize” government’s own agendas.’ (Reece, 2011, p. 224).

But what might appropriation mean? Reece suggests three out of possibly more ways of looking at this: that Government is employing feminist language to bring about non-feminist policy; that Government is using feminist language to bring about feminist goals but with non-feminist motivations and intentions; and that Government and feminists are using the same words but giving these words different meaning.

With reference back to her own point about the debate being ‘bedevilled by the difficulty of determining the meaning of feminism, that is, which and whose views count as feminist’ Reece argues that however one interprets appropriation, the problem with using this and only this to explain the resonances between feminist and governmental discourses is that ‘it relies on the expulsion of significant strands of feminism from feminism.’ (Reece, 2011, p. 227). That appropriation is nevertheless the dominant perspective within feminist writings, or at least the default position, suggests to Reece that Janet Halley analysis of contemporary feminism captures an important dimension of its nature and mode of operation:

'Answering these questions involves recognising "the profound commitment of [feminists] to an understanding of themselves as *utterly without power*" (Halley 2006, 14; see also Halley et al. 2006, 419). In relation to the 1990's in particular, Halley holds up the puzzle of "the profound rupture between the actual, real-world and theoretical power that feminism was exercising, and its experience of theoretic and institutional powerlessness" (Halley 2006, 32). Halley suggests that for some feminists this is so strong as to be a syllogism: feminism cannot hold power, therefore either feminism does not hold power or this is not feminism (Halley 2006, 344).

Halley puts forward a number of reasons for this commitment including "the proliferation on the left of minoritizing identity-based vocabularies in which high-priority political and moral claims can be made only by the "marginalized" and the "silenced"" as well as the "subordination-theoretical assumption that power is always bad" (Ibid, 14). But she goes furthest towards answering these questions when she queries "the good faith of feminists who persistently represent feminism as unequivocally a political underdog" (Ibid, 32). Such bad faith may lead to blind spots (Halley 2006, 344): "As a form of consciousness, bad faith reproduces itself and blocks the radical impulse to examine the ways in which our precommitments ensure that we'll 'see it because we believe

it.” In other words, “bad faith” could lead the data to be slotted into a pre-existing framework, rather than accorded more open-ended treatment.

Apart from anything else, this matters hugely to the integrity of academic research. But even leaving this to one side and turning to the “real world”, if Janet Halley is right that feminism has achieved real power, then it is surely crucial to notice and acknowledge this, as “a simple predicate of responsible power wielding” (Halley 2006, 14). Otherwise, feminism “wages power without owning it” (Ibid, 33); giving feminism the capacity to change social life without acknowledging, let alone agonising over, the full range of its distributive effects in the world (Ibid; see also Halley et al. 2006, 420).’ (Reece, 2011, p. 228).

Unlike Kelly and Humphreys, to take the scholars Reece focuses on, most within the STS and SSK community would accept that at the level of discourse, certainly within some areas of debate, themes associated with the Democratic Model have become a key part of the debate. Wynne’s complaint, after all, is that Government is ‘Hitting the Notes, but Missing the Music’. For Reece, to recall her point on resonances between feminist and official discourse:

‘There are (at least) two distinct ways to read any such resonances. On the one hand, they can be seen as evidence of feminist influence over or capture of policy-making; on the other hand, they can be regarded as

indicating (no more than?) the appropriation of feminist language.' (Reece, 2011, p. 223).

Analogously with Janet Halley's point about the refusal of feminism to accept influence and power, SSK's default position of rejecting influence is, I would suggest, of a piece with its self-perception as much or more than with reality. This requires further discussion and analysis of course, to which I turn next. But even if we were to accept in part the self-perception of advocates of the Democratic Model, the claim to a lack of influence may still not stand. Many in the STS and SSK community would probably sympathise with Gotell's concerns about appropriation. In other words, regarding Reece's two part distinction between those who point to direct influence and those who argue instead for appropriation, most would probably take the latter view. But this in turn only raises the issue that Reece considers in her outline of the three possible meanings of appropriation, which are, in relation to feminism: that Government is employing feminist language to bring about non-feminist policy; that Government is using feminist language to bring about feminist goals but with non-feminist motivations and intentions; and that Government and feminists are using the same words but giving these words different meaning.

The analysis of how feminism shaped larger governance policy provides an interesting comparison with how STS/SSK thinking may have influenced the

changing governance of science. In the next three sections I review the methodological strategy I employed to interrogate my research questions around this issue, and more specifically how I used the case studies to develop the analysis of the relationship between governance and Democratic Model ideas.

### **4.3 Grounded theory, the case studies and case study methodology**

As discussed in chapter one, grounded theory is well suited to analysing the case studies in this thesis. But grounded theory isn't a mechanism that generates results when one turns the handle. To give a concrete illustration of the difficulties, consider a study of professionals' views of human tissue legislation.

The authors make this claim for the grounded approach:

'Our research was qualitative and was carried out with small groups of professionals in two centres. Although this limits the generalisations that can be made from the data, we were able to identify descriptive codes that reflect the real dialogue of the professionals rather than a reduction or abstraction of their responses. The analysis of the interview data used tools associated with the "grounded-theory" approach to qualitative analysis, as described by Glaser and Strauss. Using aspects of this approach, a systematic and replicable method of analysis, strengthens the validity of the research. Given the above caveats, we do claim that our

research has revealed insights into how professionals have reacted to these changes and that it suggests ways in which the ethical dialogue may be carried forward.' (Campbell, McLean, Guttridge and Harper, 2008, pp. 107-108).

I share the authors' aspiration to reveal insights into how the world works, but I judge the claim they make for a particular method in isolation as applied to a collection of interviews to be too strong. The claim that their research results rest upon an essentially scientific and replicable approach suggests a reality test, and this poses a problem. One of the authors' main claims is that while they recognise that tensions persist, they hope that they have 'dispelled some myths about insensitivity in professional attitudes.' They suggest further that 'despite misunderstandings that have arisen on both sides, there is much in the new legislative changes that reflects a common cause and common concerns.' (Campbell, McLean, Guttridge and Harper, 2008, p. 108). Based on my own experience as a participant in debates, the strength of feeling exhibited in public and Parliamentary debate, both before and after 2006, the statements from some of my interviewees and other recent academic work (Armstrong, 2008; 2009) I would suggest that this is a particular interpretation of the debate, one that, at the very least, minimises tensions.

In many ways the strengths and weaknesses of the approach, and the issues to watch out for, are similar to those involved in using other social science methods. Campbell et al overplay the power of the approach; others underplay it or are too dismissive. I was not persuaded by some of the well-known critiques of grounded theory. Kelle (2005), rightly in my view, argues that grounded theory is not vulnerable to the charge that it ignores the 'theory-ladenness' of observation. Charmaz (2006), also rightly in my view, argues that while grounded theory works particularly well within a pragmatist philosophical framework, it is consistent with any and all philosophical frameworks. To generalise: all social science methodology is vulnerable to the charge that it is undermined by the 'theory-ladenness' of observation, and all approaches have been developed within or influenced by certain philosophical traditions and perhaps fit better within some than within others. The important point is that an awareness of these issues puts the researcher on guard rather than forces him to reject certain approaches or follow particular philosophical approaches.

What marks grounded theory out is that it can facilitate the incorporation of a number of ideas and theories into the process of building new theory. Use of it must combine empirical, interpretive and critical elements. The researcher must also be open to different interpretations and be cautious about making strong claims based on use of the approach. I used it within a framework that includes a



number of methodological and theoretical commitments and judgements, some of which have been discussed already and others that are introduced in this section.

Having considered the limitations of any claim to have clearly 'proven' an argument in a complex area of social science, it nevertheless remains the case that case studies are particularly suited to developing causal explanations. As Alan Thomas argues: case studies are a form of intensive research; they are used primarily to develop an understanding of the way in which causal processes work in particular circumstances; they are used to test an idea or ideas; and the case study methodology can be applied very well to policy processes, which are good examples of cases (Thomas, 1998). He goes on to state, and then tackle, an important objection to the approach:

'It is easy to be criticized for simply finding evidence to fit your preconceived ideas. Since you choose the case study and start with a theoretical explanation already in mind, then finding evidence to fit your pre-prepared story may appear to be a self-fulfilling prophecy. Case study research can indeed be a matter of using a mixture of mainly qualitative methods and subjective judgement to tell a story which confirms what you already worked out was to be expected. Yin (1994) argues that this is unavoidable but acceptable. The important point is to be open to the possibility that the story is wrong or needs changing. If your ideas really

are open to challenge then simply showing that as more and more detail comes to light the same basic explanation remains consistent is in itself a useful result.' (Thomas, 1998, p. 329)

Certainly, I had some ideas worked out, and I used the case studies to tell a story through developing the ideas in more detail. But I also tested the ideas, and explored some questions, some puzzles. I did this through: a thorough examination of the academic literature; 24 in-depth interviews with a range of actors collected between June 2008 and May 2011; an analysis of the 231 responses to *Human Bodies, Human Choices*; other documentary analysis; and reflection upon my own participant observation in the debate as someone working in the field for a number of years.

Michael Burawoy makes the case for what he calls the extended case method (Burawoy, 2009). This is defined by its four extensions: 'the extension of observer into the lives of the participants under study, the extension of observations over time and space; the extension from microprocesses to macroforces; and, finally and most important, the extension of theory.' (Burawoy, 2009, p. xv). For Burawoy, extension of theory is most important because that is how we make sense of the world, and because whether we make it explicit or not, it is always there.

Drawing on Karl Popper and Imre Lakatos he marries his model of the extended case method to a fairly strict idea that the purpose of research is to test, and in particular to attempt to refute, theory, or parts of a theory. In my view this model (especially Lakatos') works better as a model of natural scientific research than it does as one of social science research. But, nevertheless, his emphasis on the importance of theory is to the point, and particularly relevant to my study was this argument:

'First, we do not strive to separate observer from participant, subject from object, but recognise their antagonistic coexistence...

... Second there can be no microprocesses without macroforces, nor macroforces without microprocesses. The question is how we deal with their relationship. It requires that we recognise how theoretically embedded we are when we enter the field. Rather than seek to repress this as bias, we turn it into a resource for constructing the linkage of micro and macro. Third, history and sociology do not occupy watertight compartments; we are living history as we do research. Conceived of as a succession of revisits, participant observation is itself inherently historical – how we see ourselves today is inherently shaped by how we were yesterday. Once again theory helps us tie together past and present.'

(Burawoy, 2009, pp. 8-9).

In dealing with the relationship between the macro and the micro we look, he argues, 'upon the external field as the conditions of existence of the locale in which research occurs. Accordingly, we move beyond social processes to delineate the social forces that impress themselves on the ethnographic locale. These social processes are the effects of other social processes that for the most part lie outside the realm of investigation.' But at the same time, the locale affects, is one of the factors affecting, the external field: 'Reflexive science insists, therefore, on studying the everyday world from the standpoint of its structuration, that is, by regarding it as simultaneously shaped by and shaping an external field of forces.' (Burawoy, 2009, p. 42). But how does one, from among the many external forces at work, identify those that are most important?

According to Burawoy:

'They cannot be determined from the perspective of participant observation alone but, in addition, require the adoption of a theoretical framework for their delimitation and conceptualization. But theory is necessary not just to grasp the forces operative beyond the site but also to conceptualise the very distinction between internal and external, local and extralocal.' (Burawoy, 2009, p. 90)

Looking back on his own rather unique life and work, he came to the conclusion that a mistake he was prone to make was to pay insufficient attention to or to

reify the broader forces beyond the ethnographic site, treating them as if they were natural and external (Burawoy, 2009, p. 259).

The case studies I chose overlapped temporally, but substantially the most recent debate on embryology came after the debate on tissue. Going further back in time, in the 1980s there was a major public debate about embryo research governance, leading up to the creation of the original Human Fertilisation and Embryology Act (HFE Act 1990). One could go further back, and I implicitly do, to the 1960s and the creation of the first Human Tissue Act (1961). That both case studies had recent and not-so-recent comparators, and that the cases I studied more intensively, the most recent on tissue and the most recent on embryology, followed one another quite closely and were in important ways related, allowed consideration to be given to the ways in which Government, regulators, the respective scientific communities and the various actors interested in both areas drew upon prior experiences and resources. This pattern also allowed for consideration to be given to the framing of the debates by wider political and sociological forces specific to the respective times, roughly 1999 – 2005 and 2004 – 2008, with a further comparison back in time to the 1980s and the 1960s. Finally, it raised and allowed investigation of the extent to which, and also just how, in Burawoy's terms, forces operating beyond the site, those wider political and sociological forces, interacted with dynamics that are more internal to the cases studied.

A number of influential ideas within the contemporary literature on governance can be examined through the case studies I have chosen, approached in the way outlined by Thomas and Burawoy. Implicitly, and to a degree explicitly, themes associated with precautionary governance, participation and engagement were important in the debate over the regulation of the use of human tissue that led up to the Human Tissue Act 2004. The idea that Government and regulators engaged with the reality of a plurality of views and sought to marry different perspectives through a deliberative process was important in the debate on human embryology leading up to the HFE Act 2008, a process that also included a formal consultation by the regulator on the issue of hybrid embryos (the most expensive consultation it has ever done), incorporating deliberative elements.

That the cases are both similar and dissimilar raised some challenging methodological issues. I used the cases for the purposes of both literal and theoretical replication (Thomas, 1998, p. 324).

Literal replication means choosing cases to be as similar as possible to each other according to the conditions that are considered to be important. The two case studies I looked at exhibited similarities in some important respects, not least in the connections between the themes associated with new approaches to governance that were influential in both debates. In addition both debates were

contentious and politically charged, involving Government, politicians, regulators, natural scientists, social scientists, advocacy groups and the wider public.

Theoretical replication means choosing case studies that are different from each other in theoretically significant ways. One difference has already been touched upon: precautionary governance and related themes played a greater role in the debate over human tissue than they did over human embryos. In the view of Government at the time, research practices using human tissue had drifted into being out of sync with prevailing norms. Government disapproval of researchers' activities was a powerful force in shaping events around tissue. Further to this, a second difference is that though separated by a short period of time, changes had occurred in the context. The period around 2000, when governance of human tissue was debated, was a particularly turbulent time for the governance of science in general.

Another, third, issue to consider is that, in their own terms, the ethical issues are different or, at the very least important players in the debate cast them in different lights. As Martin Bobrow, a leading UK clinical geneticist put it during an evidence session to the Joint Parliamentary Committee scrutinising what would become the HFE Bill:

‘if one looks at the types of ethical and social issues that the two bodies deal with, they are hugely different. The HTA is essentially concerned entirely with the policing of consent, important but quite trivial in a deep philosophical sense. The HFEA with its remit to look at all aspects of embryology deals with a much wider, more complex range of issues.’

(Joint Committee on the Human Tissue and Embryos (Draft) Bill, 2007, p. 241).

Perhaps linked to the three factors listed above, there are a number of important differences between the cases in the way that events unfolded and the lessons that the protagonists have drawn, regarding in particular who was involved in the debates and on what side. Descriptively, and simplistically, in the case of tissue, Government and some patient groups lined up on one side and put the scientific community on the defensive. In the case of embryology, key patient groups and scientists worked together to bring Government and the regulator round to allowing most things they wanted, albeit under a regulatory regime many were critical of. In the latter case there was a historical precedent for this kind of alliance in the debates around embryology in the 1980s, leading up to the HFE Act 1990 (Mulkay, 1997). Embryo researcher Martin Johnson suggested during my interview with him that the different approaches of the two scientific communities was key to the way the alliances were created and the different ways in which the two debates unfolded:



'The whole business of how tissues were used by doctors to help patients never got articulated, they let the small group of patients who were very emotionally aggrieved for entirely understandable reasons make the whole case, they didn't go out and attempt to engage with them, they just hid from them, in shame almost. They shouldn't have done that. They should have gone out and said: "some of the things that have been done by our colleagues are appalling but the majority of us are not like that and this is what is driving us." That case wasn't really made; it just wasn't made. I tore my hair out – I said to my colleagues in pathology "why aren't you going out defending this, you're going to get clobbered if you don't; you have to go out and be prepared to take the flak"... In the UK on embryo research there wasn't a no go area, for the Human Tissue Act there was. You couldn't somehow appear to attack grieving parents. They didn't need to be attacked, but it could be seen as attack, and you had to accept the fact that some people would see it as attack, including some parents. People [scientists] didn't adequately engage, and they're reaping that harvest.' (Interview, Johnson, July 2008).

The important point in working through the methodological issues that similarity and dissimilarity give rise to was to be aware of, to specify concretely, the ideas that the case studies were being used to develop and test. These are outlined

and discussed in the next two sections: **4.4 Precautionary governance, participation, engagement, tissue and research**; and **4.5 Engagement, pluralism, deliberation, embryos and research**.

#### **4.4 Precautionary governance, participation, engagement, tissue and research**

My primary focus in this case study was to develop an analysis that identified influences from wider debates on the governance of science in the aftermath of the BSE controversy on the development of governance in the context of human tissue research, and how in turn debates over human tissue moulded those general frameworks. With this aim in mind, in addition to examining the role of the media and patient groups I paid close attention in my interviews and in my research more broadly to the relationships between those who had a pre-existing critical attitude towards medical and medical research practice on the one hand, and Government and governance agencies on the other. At a theoretical level, I worked through the relationships, both intellectual and interactional, between the approaches and activities of STS / SSK theorists and theories on the one hand, and normative theorists and theories, such as human rights-based perspectives, on the other. Does the tissue case study suggest direct influence or at the very least STS language and ideas being used to bring about goals in line with STS thinking for non-STS reasons?

A plurality of approaches to, ideas about and analyses of particular issues related to research using tissue have always existed. Ethical, legal, cultural and sociological analysis of human tissue is one input into the public discussion of and a contribution to the construction of governance of human tissue research at any given time. Precautionary approaches can create a space for critical approaches to influence policy and governance. However, precautionary governance as a process involving powerful state and regulatory bodies also moulds and shapes those critical influences when they enter the policy debates – through engagement with the political and policy process the issues, ideas and questions addressed by the full range of interested parties, including the critical ones, have in fact in part been framed by these ongoing processes. Account needs to be taken of this moulding when considering the appropriate measures of influence on governance and changes in governance.

What, in a little more detail, is precautionary governance? For the editors of *Late lessons from early warnings*, the precautionary principle 'is playing its part in the development of civil society and policy-making during the early 21<sup>st</sup> century which, it appears, will have its own distinctive character, as great in its differences as those which set apart previous centuries.' (European Environment Agency, 2001, p. 189). Critics of the principle also endorse the overarching importance of the idea. Mary Douglas and Aaron Wildavsky pointed a number of

years ago now to the different ways in which we can think about the future.

Precautionary thinking is a particular way, one that is in fact quite novel historically speaking: 'in the [19<sup>th</sup>] century, prevailing opinion held that the future would have better solutions for its problems than the present generation could devise. They rejected "overconsuming safety" in favour of allowing the future to decide for itself.' (Douglas and Wildavsky, 1982, p. 23). Alaszewski and Burgess take up and expand upon this historical comparative, and critical, approach:

'From the late twentieth century, a more precautionary approach has emerged, in which the fear of future harm influences the management of risk. If a sense of risk is historically bound up with the emergence of probabilistic thinking and an orientation toward the future, that orientation has become less open-ended in a precautionary approach that casts the future principally in negative, potentially catastrophic terms.' (Alaszewski and Burgess, 2007, p. 349).

How does the precautionary principle fit together with governance and then with participation? According to Lyall et al, as already noted, governance is now widely understood to entail 'an increased role of non-government actors in policy-making through various participatory networks and mechanisms.' This perspective foregrounds governance as 'an inherently political process, concerned with articulating different actors' interests, values and beliefs' (Lyall,

Papaioannou & Smith, 2009a. p. 261). Combining precaution and governance to gain an understanding of process, Sue Oreszczyn, in her study of precaution and GM crops, argues that the precautionary approach adopted in the UK helped to facilitate the process of including different actors in the governmental process (Oreszczyn, 2005).

But how did it help, and in what way? Given the ideas it embraces, adopting a precautionary stance opens up a dialogue with groups and interested parties, encourages their participation, in a particular way. Precaution involves certain assumptions about risks and harms. It is not a simple matter of Government listening to the (precautionary) sentiments of groups and interested parties: precautionary governance is an invitation to respond with concerns and problems, and a license to listen to those who do raise precautionary concerns more than those who do not. Precautionary governance played a clear and obvious role in the conflict over GM crops. For Miller and Conko, this approach led to unreasonable restrictions on what they considered to be a safe technology:

‘As a tool of public policy, the primary shortcoming of the precautionary principle is that it incorporates neither coherent evidentiary standards nor any clear stopping points... it effectively frees regulators to arbitrarily require any amount and any kind of testing they wish; likewise it permits

them to ignore overwhelming evidence of a products' (or a technology's) safety and to prevent its use.' (Miller and Conko, 2000).

While different in a number of ways, the debate over research using human tissue in around 2000 – 2004 has some similarities with the debate over GM crops and food. Research using human tissue became controversial at roughly the same time as the debate over GM reached a pitch of intensity, it was framed by some of the same political and governmental dynamics, and, echoing the mutual dissatisfaction evident in the debate over GM, both proponents and opponents of a root and branch reform of the culture and practice of research were disappointed by the final Act. McHale (2005) called it a 'missed opportunity,' while Price (2005) felt that the initial purpose of the Bill had been heavily compromised. On the other side many tissue researchers felt they had been treated badly by the political process surrounding the Bill and are still angry about the Act. An important issue for me to research was the reach-through of political debate on the Bill to the terms in the Act and to the practice of the Human Tissue Authority (HTA). What could it mean, for example, to consider the HTA as embodying a precautionary and participatory approach to governance?

#### **4.5 Engagement, pluralism, deliberation, embryos and research**

My primary focus in this case study was to develop an analysis of the continuities and changes in the governance of embryo research, and in particular the influence or non-influence of themes associated with the Democratic Model on the process of the renewal of embryo research governance. This process began around 2005 with a Parliamentary inquiry into the legislative framework, which in turn developed into a focused Governmental consideration of the issue spanning approximately two years. Initially a Bill was drafted that would have covered both human tissues and embryos, and would have established a new regulator for both areas. This proposal was dropped and a narrower Bill was proposed and passed by Parliament (the HFE Act 2008), essentially updating the HFE Act 1990. During this period the debate turned into a wider public one and included controversy over particular issues. Despite many formal or surface continuities with the debates of the 1980s, has the new governance framework in substance moved away from its old framing based on the moral status of the embryo into more normal, and normally problematic, patterns characteristic of other areas of science? Does the embryo case study suggest that some SSK themes directly influenced the process of governance renewal and the resulting framework, or

was it more a case of Government using ideas associated with the Democratic Model for different ends?

As compared with the regulation of research using human tissue prior to the HT Act 2004, prior to the HFE Act 2008 research using human embryos was more clearly and strictly regulated under the terms of an existing Act of Parliament, the HFE Act 1990, though there was a feeling that the legislation was becoming a little worn; that it was struggling to cover new developments. And in so far as the scientific community was closely involved in the process at the start, it was pushing, tentatively, for a liberalisation of the regulatory regime, a more 'research-friendly' regime, rather than fighting to be heard in the midst of a controversy as with the debate over human tissue. Consonant with the scientists' hope that they might be able to nudge the regulations in a more liberal direction, broad support for the principle of research using fully human embryos was evident throughout the debates leading up to and on the Bill, and in one way the 2008 Act is more liberal than its predecessor, in the sense that it allows a wider range of research activities than the 1990 Act. But that is only half the story. One issue came to dominate the public and political debate on research, the debate over hybrid embryos; that is, embryos combining human and animal material. In this debate the research community found itself fighting a rearguard action to prevent what it saw as a thoroughly misguided proposal from Government to ban their use.



True hybrids, resulting from the mixture of human and animal sperm and egg, is one kind of hybrid, but the kind that was most widely debated, largely because it was the kind that scientists, or some scientists, had the most interest in pursuing, is the kind that is formed by the transfer of a human cell nucleus or the entire contents of a human cell into an enucleated animal egg cell. This process, cell nuclear replacement [CNR], is based on the technique pioneered at Roslin in 1996 using cell nucleus and egg from the same species (in the Roslin case sheep). Human admixed embryos of this kind have been called cybrids.

In the end the research community persuaded the Government to back down, but at the cost of re-enforcing the legitimacy of the regulatory structures about which some scientists had been very critical. The HFE Act 2008 allows human admixed embryos to be created and used in research under licence from the regulator, the Human Fertilisation and Embryology Authority (HFEA), in effect treating them as if they were fully human embryos, but at the same time distinguishing them.

Overall, attempts to liberalise the regulatory structure failed: the character of the HFE Act 2008 is substantively similar to the HFE Act 1990, and formally speaking the underlying philosophy of the 2008 Act is the same as the 1990 Act, which was based on the work of the Warnock Commission in the 1980s (Warnock, 1985).

However, in addition to the formal and substantive continuities between the recent Act and the 1990 Act, there have also been some changes in the processes of governance. Attention back in the 1980s was focused on the status of the human embryo and the limitations that should be placed on embryo research because of this. There was limited enthusiasm for re-hashing that debate prior to the 2008 Act, and in substance it is not at all clear that regulation and restrictions on research relate directly to it. Rather, Government, for example in its White Paper (Department of Health, 2006) and in Ministerial speeches on the Bill, tended to employ second order arguments: setting boundaries to what could and could not be done with human embryos was necessary, it was argued, in order to give respect to a plurality of views and in order to meet the twin aims of supporting research and meeting public concerns.

The setting of boundaries by Government combined with the emphasis on renewal through deliberation places the process firmly within the framework suggested by Peters (2011) and Lyall et al (2009). In their conclusion, Lyall et al highlight the following set of issues, but also suggest something more:

‘Governance, as both a process and a vision of how the state and society ought to interrelate, profoundly reflects the dynamism of change in all its facets, political, economic, societal, and this dynamism is thrown into yet

sharper relief by the challenges laid before us by the life sciences.

Capturing this dynamism is precisely what governance – as an effective policy process – should be doing. But, what many chapters have demonstrated, is that this remains both problematic and increasingly necessary.’ (Lyall, Papaioannou and Smith, 2009a, p. 265).

In this quote tensions within governance are pointed to but governance is also projected as an overall framework for the relationship between the state and society, for how the state and society ‘ought to interrelate’, with a focus on governance ‘as an effective policy process’. This appears to be a somewhat different approach to governance to the one mapped out in Tait’s contribution to the same collection, the editors’ introductory chapter and also other parts of the editors’ concluding chapter. It seems more in line with an ideal, perhaps how Laurie, Bruce and Lyall (2009) approach the issue in their contribution. In Tait’s piece (Tait, 2009a) and the introductory chapter the emphasis is on governance following from the hollowing out of the state. The relationship between governance and Government is described, and the tensions that follow from this highlighted. In the above quote, though the state is mentioned, governance is presented as enveloping both state and society (thus subsuming Government?) and is also presented as an ideal (‘how the state and society ought to interrelate’). The authors appear to be suggesting that an idealised form of

governance could smooth over the Government / governance tension and should be a political aspiration.

Perhaps, taking the book as a whole, the editors are in fact counter-posing deliberation to stakeholder engagement. In other words, perhaps they see the former as a good thing but the latter, in the context of science and biotechnology in particular, as problematic or potentially problematic. They are quite critical of some stakeholder engagement processes, pointing to the non-democratic aspects of some of them. But perhaps many of the problems that beset stakeholder engagement also beset deliberation? This is an issue I explored through this case study, by considering deliberation and deliberative processes as a part of and as influenced by the political process rather than as mechanisms standing above and for the resolution of conflict.

A deliberative approach including a public consultation was cited as the background for the proposals in the White Paper, including the proposed ban on the creation of hybrid embryos for research. More favourable public opinion expressed during detailed and informed consultation and deliberation (Human Fertilisation and Embryology Authority, 2007; Warburton, 2007) along with a reasoned case made by scientists is one explanation for the shift in the Government's position on hybrids in 2007.

In the hands of Government and regulators deliberative processes often have a distinctly managerial character. The public were still quite doubtful about allowing research using hybrids in the results published by the HFEA, but it was also clear that objections were not strongly held, that people could be won round through an emphasis on the medical benefits that might follow the research. The decisive factor seems to have been a change of heart at the top: there is much anecdotal and suggestive evidence that the regulator, and by this time Government, was committed to interpreting the consultation so as to allow research, if at all possible.<sup>1</sup>

Contemporary deliberative processes cannot be viewed as standing above the political process, as mechanisms to resolve conflict. But neither can they be dismissed with a cynical shrug. Taking the ideas seriously and analysing the processes seriously should mean subjecting them to critical scrutiny in a more substantive way than contrasting rhetoric with practice and results. A fruitful critical approach in my research was to analyse the idea of deliberation analogously to the STS / SSK discussion of reflexivity, which includes, but is not confined to, approaches which unsettle claims to academic virtue and privileged knowledge (see, in particular, Lynch, 2000).

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<sup>1</sup> The latter point was given an airing on the *Today* programme, 26 April 2007. With characteristic force, Simon Jenkins stated that 'the process (consultation) is usually completely cynical.' A press release from the HFEA on the same day stated that public opinion would inform its decision but that it would not determine it; that it was important to understand public concerns to help ensure that public 'support and trust' in research was maintained. In November 2005, roughly a year before the Government proposed a ban, the authority had argued that research using hybrids should be allowed under license in its submission to the Department of Health's consultation on the Review of the HFE Act.

## 4.6 Summary

In this chapter I began by outlining in broad terms some contemporary discussion of what has been called the new modes of governance, and situated, again in broad terms, my own approach within that. Then, to establish in more detail how I approached the issues and to explain how I understood and used the case studies, I discussed: governance and governance agencies; how to analyse influence, especially the influence of Democratic Model ideas and why a comparison with some strands of feminism might be particularly fruitful in doing that; and grounded theory and case study methodology. Finally, I outlined the particular themes I examined through the two case studies. I now turn to look in detail at the first case study, research using human tissue.

## **Chapter Five: Precautionary governance, participation, engagement, tissue and research**

‘Fundamentally, there was a social and ethical time bomb waiting to go off. It is no surprise that the explosion of anger when it came was huge. The cause lay in two conflicting attitudes. For the parents of a recently deceased child, human material, certainly substantial specimens such as organs and parts of organs and even smaller samples, are still thought of as an integral part of the child’s body and thus are still the child. For the pathologist and the clinician the material is regarded as a specimen or an object. It is dehumanised.’

**Ian Kennedy et al, 2000**

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In earlier chapters of this thesis I have already analysed a number of aspects of the debate on human tissue research. I have briefly evidenced the issues from the perspective of some of the participants and discussed some of the work of some academics who have written on the issue. Broadly speaking I have focused on the discourse around human tissue. In this chapter I move to a more substantive discussion of: underlying philosophical, social and legal theory relating to tissue governance; the substance of governance itself; and the consequence of this for research using human tissue. As a broad organising

principle I start from Dewar and Boddington's point, discussed in chapter three, that two themes were prominent in the discourse around Alder Hey: that of the mad, bad, scientist; and the idea of residual feeling in the dead or parts of the dead. In moving from an analysis of discourse to a consideration of the substance of governance I modify the first point to consider the less dramatic but probably more significant point that, in contemporary discourse and governance research as an activity has been singled out for particular, and particularly critical, attention. Relatedly, I extend their second point to consider the ways in which the status of all tissue has been raised. These two processes, I will show, were heavily influenced by a combination of Government and media activity, and academic analysis and activism. While much of this chapter implicitly addresses my second research question on the impacts of contemporary governance regimes on natural science research, towards the end I also reflect on issues relevant to my first research question, in other words how STS / SSK thought (and critical rights-based approaches) have influenced governance and policy in this area.

With particular reference to the Human Tissue Act, a number of academic writers have argued that changes to governance are not in fact that dramatic, certainly that they are not as harmful to research interests as some scientists claim. In this chapter I present the evidence I have collected, to consider, and challenge, arguments on this point from Roger Brownsword, Margaret Brazier, Sheila



McLean, Graeme Laurie and Jean McHale in particular. I also make some suggestions about why the critics of previous scientific practice fail to see significant change.

I begin, in 5.1, with a critical analysis of the arguments made by others for elevating the status of tissue and restricting / demoting research. The novelty of these ideas, or at least the challenge they posed to mainstream, especially natural scientific, thinking and practice, is outlined. Section 5.2 looks at those participants who argued for change and why the proposals had limited connection with public concerns. As Dixon-Woods observes, there was a great deal of speaking for the public and performing the public. In this context the role of Democratic Model ideas was particularly important: the issue was less about participation understood in a literal sense as it was about participation performed by Government and others. Section 5.3 focuses on the Human Tissue Act and the consequences for human tissue research. The concluding section, 5.4, summarises the main theme of the changing governance of human tissue research.

## **5.1 Elevating tissue, demoting research**

The events at Alder Hey hospital in Liverpool fully came to light during the Inquiry into paediatric heart surgery at the Bristol Royal Infirmary in the late 1990s. The

report into Bristol noted that the press and other media gave considerable publicity to the evidence of Professor Anderson to the inquiry, in which he described the various collections of tissue, which existed around the country. 'No doubt with the best of intentions', argued John Bennett, a former consultant gastroenterologist,

'to show that such collections were normal, the unfortunate Professor Anderson happened to mention a large collection at Alder Hey Hospital, Liverpool. It was soon discovered that the Professor of Foetal and Infant Pathology, Dick van Velzen had built up huge numbers of organs between 1988 and 1995. The hospital was sluggish in responding to hundreds of resultant enquiries from parents, who formed a support group – Parents Who Inter The Young Twice (PITY II). Pandora's Box was open.' (Bennett, 2001, p. 167)

Attention initially focused on Alder Hey, but, as Bennett suggests, it could not be assumed that practice there was atypical. Or at least it became important and necessary to discuss just what was and was not unique about Alder Hey, and acceptable and unacceptable about wider practices. Quite quickly, a new language came to be used in professional as well as public discourse, and a new light cast on professional practice:

'It is doubtful whether any physician used the term "organ retention" before two years ago. The study of whole organs (fresh, or preserved in jars) and histological slides has been an integral part of medical education for centuries, and every undergraduate medical school had a pathology museum of which it was often justifiably proud.' (Bennett, 2001, p. 167).

What seemed relatively simple and straightforward to the medical profession and researchers prior to the mid 1990s became complex and fraught after Alder Hey. The governance of all tissue held in storage and used for research was re-examined, in the course of which the status of human tissue was made into a public issue. In the remainder of this section I draw attention to two broad categories of analysis of or approach to human tissue that have come to the fore in academic and other writings on the topic, both of which elevate the status of tissue and demote the status of research. The first one revolves around ideas associated with privacy rights, the second with commodification. The two are linked but distinctive.

### **5.1.1 rights and privacy**

The complexities involved in analysing privacy (and property) rights in human tissue have been widely discussed by a range of scholars (see, among others, Mason & Laurie, 2001, Skene, 2002, Harris, 2002, Brazier, 2002, Herring & Chau, 2007, Manson and O'Neill, 2007, Price, 2009 and McHale, 2011). I discuss

them in a little detail in section 5.3 below. For the moment though, distinguishing the influences of the different approaches within governance is less important than highlighting the fact that all the suggestions achieve the following: (1) elevate the status of human tissue; (2) place restrictions on research to one degree or another; (3) run counter to previous assumptions and presumptions widely held within the medical research community.

The shift brought about by the linked ideas of rights and privacy can be highlighted by the critical analysis of these issues by the distinguished philosopher Onora O'Neill, who has a long-standing and deep interest in philosophical, ethical and legal issues involved in medical practice and research and has written extensively on confidentiality and rights. Many natural science researchers in particular agree with much of her analysis. In a recent book co-authored with Neil Manson (Manson and O'Neill, 2007) she outlines a defence of what might be called the pre mid-1990s consensus, through a critical examination of rights-based approaches to informed consent. Manson and O'Neill do not pull their punches. They begin by stating that: 'the quest for wider scope, for higher standards, for better justifications and for regulatory reinforcement, which aimed to make consent the lynchpin of biomedical ethics, has created intractable problems.' (Manson and O'Neill, 2007, p. 2). They conclude by claiming that 'although the details are complex, we believe that everyday views that practitioners, patients and research subjects take of

informed consent, and of the reasons why it matters, are closer to the picture that we have offered than they are to the more fashionable views that we have criticised.’ (Manson and O’Neill, 2007, p. 2).

It is important to remember that informed consent was introduced to set standards for invasive procedures that carry risks as well as benefits. However, in the last fifteen years, they note, this has been extended to secondary use of information and tissues. In this application, they argue, the original purpose and importance of consent was subverted:

‘If we think of communication as the conveyance, disclosure, broadcast, or even *communication* of information (with the conduit metaphors in play), we radically downplay the importance of the rich set of background commitments and competencies that are essentially involved in the activity of communication...

...Talk of *conveying* information from one party to another hides the fact that *what is conveyed* is not merely content, but specifically *propositional* content. We inform each other – we convey information – that certain things are the case, or that certain things would be good to bring about, or that certain things are possible, unlikely, impossible, hard to countenance, and so on...

... Much current thinking about informed consent is problematic in a number of ways. In particular, it does not take enough account of the ways in which communication rests upon a rich, but largely implicit, framework of assumptions of different kinds and at different levels.' (Manson and O'Neill, 2007, pp. 39, 43, 48)

Concretely, so far as research is concerned, for Manson and O'Neill an agency model of informing and communicating provides 'a framework for a clearer account of the point and the limits of informational privacy, and of the relevant rights and obligations. It also offers advantages in thinking about second-order obligations to assure respect for informational privacy, and suggests that a focus on norms of *confidentiality* may have a number of advantages over appeals to *data protection* requirements.' (Manson and O'Neill, 2007, p. 99) Further to that, in the research context, 'nobody has the slightest interest in making facts about any individual known. For example, a great deal of medical (not to mention other) research *uses* information about identifiable individuals for entirely *impersonal* ends... Yet if we think that individuals have a right against others possessing and using their "personal" information, such studies will be seen as breaching that right, and may seem to require consent from each individual whose data are held or processed.' (Manson and O'Neill, 2007, p. 109).

Various solutions within a, broadly speaking, rights-based system of thinking and governance have been proposed by those who recognise some of the practical and philosophical problems. Through couplets, Manson and O'Neill point to, as they see it, the limitations of these solutions. For example:

'Those who seek to interpret individual autonomy minimally as *mere, sheer choice* may be able to show that informed consent operationalises autonomy conceived in this way, but will find it hard to show that this conception of autonomy is fundamental to ethics. Those who interpret individual autonomy more ambitiously as some form of rational or reflective choosing may be able to make a better case for thinking that it is fundamental to ethics, but will have difficulty in explaining how it can be operationalised by informed consent requirements.' (Manson and O'Neill, 2007, pp. 19-20).

'It might seem that the obvious solution is to insist upon *anonymisation* of personal data, so as to ensure that it does not fall under *DPA 98*.

However, weaker forms of anonymisation do not satisfy the requirements of the Act, and stronger forms do not meet the needs of research.'

(Manson and O'Neill, 2007, p. 116).

Manson and O'Neill paint things in very black and white terms. In practice, governance regimes allow some scope for fudging things, for getting around the apparent strict requirements of the DPA 98 and other right-based instruments and procedures, or for satisfying them in ways that are not as detrimental to research interests as one might imagine, at least in principle. Some of these are discussed in section 5.3 below. Nevertheless they point to some important conceptual issues and to some very significant barriers to research practice. At the same time they highlight the significant shift that has taken place in the past twenty years in thinking about human tissue and research.

### **5.1.2 Gift, commodification and property**

A related shift in thinking about research using tissue can be located in social science critiques of gifting, in particular gifting as understood and promoted by Richard Titmuss.

The idea of gifting tissue, whether for treatment or research, has been analysed and critiqued with reference to two notions of gifting, developed and analysed by Marcel Mauss and Richard Titmuss respectively. Mauss is a reference point because he studied gifts imbued with meaning, primarily in pre-modern societies. Titmuss' focus was more recent, the study of blood donation within a welfarist context of mutual obligation after World War Two. Titmuss himself drew upon Mauss' work while also being aware of differences in context and meaning. For



those critical social scientists that reference both writers, Mauss' work is more drawn upon and endorsed than critiqued and Titmuss' more critically examined and rejected, in part or in whole. While perhaps appropriate in a welfarist context, the argument goes, the contemporary use of Titmuss' idea of gift by health services and others is problematic in today's world because Titmuss' idea of gift creates a one-way relationship when commercial entities are involved, as they increasingly are: the patient or the member of the public gifts their tissue to someone else, who in turn commercialises and makes a profit from it.

It is in casting a critical eye over Titmuss' notion of gifting that Mauss is sometimes drawn upon. However, the application is often forced. Mauss described a world in which exchange of gifts was bound up with powerful meaning and symbolism; the mis-use of his work lies in the failure of contemporary writers to adequately acknowledge that to contemplate transferring ideas and conventions from that world to our own rips them out of context and takes away their meaning. Mauss did, in the conclusion to his study, suggest that the obligations that the giving and receiving of gifts in modern societies are felt to create carry with them an echo of social life in some pre-capitalist societies. He also suggested that there are virtues in this. However, the main thrust of his analysis was that the treatment of objects in such societies was a component part of a way of life and a world-view that was radically different from our own in modern Western societies (and he was of course writing in the inter-war period).

In these earlier societies gifts came morally, physically and spiritually from a person, creating an obligation to give in return:

'The thing given is not inert. It is alive and often personified, and strives to bring to its original clan and homeland some equivalent to take its place... Thus we see that a part of mankind, wealthy, hard-working and creating large surpluses, exchanges vast amounts in ways and for reasons other than those which we are familiar from our own societies... Nothing is casual here. Contracts, alliances, transmission of goods, bonds created by these transfers – each stage in the process is regulated morally and economically. The nature and intention of the contracting parties and the nature of the thing are indivisible' (Mauss, 1970, pp. 10, 31, 58-9).

If Mauss' work is of limited direct relevance because he was writing about radically different kinds of societies from our own, an obvious alternative for those critical of Titmuss' notion of gifting is Marx's writings on exploitation and commodification. Under Titmuss' scheme, argue Waldby and Mitchell (2006), the solicitation of an unconstrained gift of material from the patient or member of the public with or without general consent, allows him or her to be excluded and turns the body into an open source of biological material for commercial use. Or as Donna Dickenson puts it, the patient is the altruist, while everyone else is a capitalist. In short, the commodification of tissue leads to the prospect of

exploitation of the tissue donor (Dickenson, 2009). As with Mauss, however, this application of a Marxist framework is at least in part historically and theoretically one sided, if not altogether flawed. Consider first some blindspots in an historical analysis.

In an afterword to her famous study of the 1832 Anatomy Act, *Death, Dissection and the Destitute*, Ruth Richardson (Richardson, 2000) covered contemporary issues, including Alder Hey, which was just breaking at the time of writing. She saw some direct comparisons between the past and the present. She was especially bothered by presumed consent and also the possibility that an international trade in tissue and organs could include not only the things we know about – poor people selling tissue and organs while alive – but worse, including murder. But how persuasive is her history, and of what relevance is it to analysing Alder Hey?

There are two significant problems with or at the very least tensions in her analysis of the contemporary situation, problems that run through similar analyses by other writers. First, the use of past practices and abuses as a suggestive framework to understand the present, despite an awareness of dramatic changes over time, and secondly a lack of clarity about just what the contemporary issue is, informed by a partial or particular reading of the past.

In discussing the context for and opposition to the 1832 Act, Richardson insists that to 'appreciate the meaning of this material, we must come to terms with our own hostility to superstition... The significance of the human corpse in popular death culture at the time of the Anatomy Act seems to have been coloured by a prevailing belief in the existence of a strong tie between body and personality/soul for an undefined period of time after death... the result was an uncertain balance between solicitude towards the corpse and fear of it.'

(Richardson, 2000, p. 7). This combination of solicitude and fear was mixed with strong and distinct class issues, argues Richardson, drawing on the writings of Marxist historian E. P. Thompson. Primarily it was the bodies of the poor that were gathered and stolen for research, and in some instances the poor were killed and their bodies sold for medical research.

Richardson suggests that this history is of some relevance to the present, in particular the meaning of Alder Hey. But she herself believes the context today to be radically different. Society's attitude towards the corpse has changed dramatically: bequests came to dominate after the Second World War, and a marked trend towards this situation began between the wars. At the same time cremations became more popular. This, she says, marked a big change in attitudes towards the corpse:

'More research is needed before the reasons behind this change in public attitudes are fully clear. That there occurs over a closely similar period an almost parallel rise in the popularity of cremation suggests that the social meaning of the corpse and its spiritual associations has changed, and that the key period in which this change occurred preceded the Second World War. Both trends bespeak a growing disbelief in the spiritual coherence of the corpse. The increase in bequests suggests in addition a more benign public view of scientific medicine. The possible influence of changing attitudes of government towards poverty – particularly evident in the abolition of the Poor Law Board in 1929 – cannot be ignored. Further work will need to be done to see whether the meteoric post-war rise in bequests bears an association with the establishment of the NHS in 1948, or of the Death Grant in 1949, as would seem to be likely.' (Richardson, 200, p. 260).

And while the Anatomy Act is still in force, 'bequests of bodies now ensure that the social injustice it represented before the Welfare State no longer operates.' (Richardson, 2000, p. 283). As is clear from these quotes, Richardson believes that much has changed, which must surely cast doubt on the use of the past as a framing mechanism for the present. But how reliable is her reading of the past, or rather, for she is fairly open about this, what are her biases? While drawing heavily on E. P. Thompson, she doesn't much care for some of the strands of

working class opinion that Thompson documents. Referencing chapter 16 of his *The Making of the English Working Class* she acknowledges that some working class radicals did not share in the repugnance towards dissection. Her dismissal of the radicals is rather poor. She presents them, essentially, as dupes of the Whigs and the Benthamites: they 'acted effectively in support of the ruling elite in the successful redefinition of poverty as a crime, and the use of dissection to terrorise the poor.' She goes on to praise an analysis by Roger Cooter. Here's an extract from a longer passage she quotes:

"the radicals' faith in science as a levelling resource directed against aristocracy and clergy was an effective source for their cultural exploitation by the radical bourgeois promoters of science... Failing to perceive the ideological power that Reason had assumed, artisans became its victims... destined to promote and safeguard the Reasonable bourgeois world." (Quoted in Richardson, 2000, p. 153).

Of course Richardson and Cooter have a point: the Anatomy Act was loaded with class prejudice and can be located somewhere on a continuum with practices that extended to the appropriation by one means or another of the bodies of the poor. Nevertheless, this can be separated from the distinct point about superstition and attitudes towards the corpse, which was of course the radicals' main point. What seems clear is that Richardson's own social agenda and

attitude towards the poor has some if not a lot in common with Tory paternalism, from which source some opposition to the Anatomy Bill came.

In addition to drawing explicitly on the past, Richardson suggests parallels through mentions of the categories commodification, reification and alienation, though she does not discuss them in detail or explain what she understands by them. This is not untypical in fact: one finds these terms used in a wide number of texts on the subject of human tissue research absent detailed theorisation of them (see for example Sharp, 2000, Lock, 2001). And in popular and media discussion too, which can lead to a process of reinforcement. As Seale, Cavers and Dixon-Woods observe: 'media reporting of child organ retention scandals in the UK in recent years has made an independent contribution to the commodification of body parts, recruiting them for use in the manufacture of a media scandal. Ironically, the scandal was itself about the objectification of children's body parts by bio-science.' (Seale, Cavers and Dixon-Woods, 2006, p. 37). There is an important observation in this analysis, but also a question-begging component: how was it a 'scandal' in the first place, and how did it involve commodification?

I discuss the social construction of the response to Alder Hey later in this chapter. In concluding this section I discuss very briefly the second aspect of the use of Marx's writings, the use of his ideas on commodification and his analysis of

commodity production and exchange in capitalist societies. According to Donna Dickenson: 'Marx distinguished first between attributing "use value" to something, *objectifying* it, and, additionally, making it an object of exchange, *commodifying* it.' She goes on to argue:

'What is wrong is making a saleable object of something that should be treated as having value in itself, irrespective of what use might be made of it. Because people have value in themselves, parts of people, you might think, would be particularly problematic. If it's wrong to make people into objects or things – as slavery does – and if the body is the person, then is it wrong to trade in bodies and their parts?... Once the body is viewed as a fully-fledged commodity, we will lose our sensitivity to abuses like many of the cases in this chapter. Then it will become much harder to draw the line, as proponents of regulated body shopping want to, between rightful and wrongful kinds of trade in bodies. Why shouldn't dead bodies then be viewed as one of the rightful objects? Or embryos ranged in a bank like dresses on a clothes rack? Drawing fine lines, like the one between "custom-made" and "ready-made" embryos, will more readily become the order of the day, once we admit that body tissues can legitimately become commodities. And some of those lines will be very fine indeed.'

(Dickenson, 2009, pp. 11; 21):



The problem here is that Dickenson has smuggled an ethical presumption about tissue into the analysis without fully arguing for it. For Marx, the issue was not so much objectification or commodification but rather a general theoretical notion that a commodity must possess a use value – it must be useful for somebody other than oneself – and it must possess a value, a converted form of which is market price. Dickenson's primary objection appears to be that a use value for others is stamped on something, tissue, which should primarily be seen as of personal and intrinsic value to the original donor outside of market relations. But why should I 'value' a bit of blood or some other waste material (from my point of view) in such a way that I do not wish it to be traded? If the issue is coercion of different kinds to give up and trade whole organs or a debate about the rights and wrongs of trading human eggs, then that should be discussed as such, rather being swept up in a general claim about the special status of all tissue. That would spoil the construction of course. In Dickenson's and others' argument, the main work is done by extreme examples, such as poor people trading whole organs or poorer women in particular trading eggs (Dickenson, 2009), and the famous case of John Moore and the very valuable cells derived from his spleen, reinforced by slippery arguments down a slippery slope to references to a, we must assume, somewhat sinister global trade in tissue and body parts (Waldby and Mitchell, 2006). There is something troubling if not clearly objectionable in the hyperbolic language and lumping that occurs in some of the commodification literature, such as in Sharp for example: 'within the United States, slaves have

been marketed as breeding stock, and athletes and their teams are frequently bought and sold by elite clients... The medicalization of life, the fragmentation of the body, and the subjectification of colonized subjects all potentially dehumanize individuals and categories of persons in the name of profit.' (Sharp, 2000, p. 293).

## **5.2 Driving change by speaking for the public**

In addition to theoretical problems with the commodification literature and issues of bad taste, there are steps in the argument that are in reality simply assertions, assertions that once examined reveal empirical failures or gaps. A key one, which links the commodification literature to the rights literature, is the very idea that the public want to be or should be asked about the use of tissue. There are many areas of life where we are not asked about things that are done with information about us, or indeed with former possessions, especially ones we might consider waste. That last word, waste, is a provocative one to some rights thinkers and social scientists in this area, because it is their contention that natural science researchers have treated our body parts, tissues and cells as if they were waste. But if they have, would it be a problem, and if so why? If I am not disrespected when my household waste is used by large faceless corporations as a part of disposal and recycling processes, why am I disrespected if my excised body parts, surgical tissue, spit, urine, blood, faeces

etc are used in research and commerce without my consent? Moreover, perhaps I positively want the medical profession to make use of something I see as waste? (For a discussion of this, see Dixon-Woods, Wilson, Jackson, Cavers and Pritchard-Jones, 2008).

In the background then to rights arguments, some social science analysis and commentary covering the full range of kinds of human tissue there lurk concerns about coercion, medical power and commerce, and a judgement that it is not just about asking, it is about asking or not asking about things we might reasonably think are important and sensitive materials or issues. Mixed into the analyses are empirical claims, or assumptions, such as the idea that people want to be asked; want to be asked in some detail, and will soon stop donating tissue if this exploitation of their generosity is not curbed.

In this section I dig deeper into these issues, examine how they informed proposals for legislative reform and show that Government drew on them to drive change. In support of this argument, inter alia I discuss the key consultation document *Human Bodies, Human Choices (HB, HC)* and the responses to it. With this document and the Government's handling of the responses, it became clear that wide ranging legislative reform would take place, on a basis the medical profession found quite shocking.

As discussed in chapter two, Richard Tutton, like many other STS and SSK writers, thinks that ideas associated with the Democratic Model have had little impact on natural science governance. However, while somewhat equivocal, he thinks that in the case of human tissue research there might have been some impact, or at the very least he is hopeful that this might have been the case:

‘Some recent innovations in governance would suggest that policy advice and regulation has become more “participatory”... Created under the terms of the Human Tissue Act 2004, the UK Human Tissue Authority is a statutory body responsible for regulating and licensing the use of human tissue for a range of purposes from transplantation and pathological examination to research. The HTA emphasizes that, of its 16 members, the Chair and nine others are not from medical professional backgrounds but are individuals with experience in the voluntary sector, NHS user involvement and patient or public advocacy groups.’ (Tutton, 2009, pp. 56-57).

As Tutton suggests in this quote, we need to consider what has been done with the idea of participation by governance agencies in addition to thinking about the idea in literal terms, and we also need to think about context, for whether understood literally, performatively or as a combination of the two, patient and public participation does not occur in a political and sociological vacuum. The

urge to develop such approaches and the directions taken are influenced by the roles played by various ideas and actors.

Human rights discourses, commodification and a critique of gift relationships as theorised by Richard Titmuss provide a set of principles that some think should guide and restrict research practices, a set of principles and ideas that also informed many of the proposals for participation and involvement. Michael Steinmann, introducing the edited collection *Altruism Reconsidered*, highlighted some of these connections in the thinking and work of the contributing authors:

‘Lenk and Hoppe suggest a normative model for the use of human tissue. This model relies on the special dignity of the human body. Body parts cannot be used without the voluntary and informed consent of the donor. This means that any kind of “blanket” consent has to be rejected. “The normative objective”, according to the authors, “is cooperation between researcher and patient for the benefit of research”, including the need to establish ways of benefit sharing. As in previous chapters of this book, the idea of a one-way relationship between donor and recipient is replaced by a more participatory notion of their relationship.’ (Steinmann, 2009, pp. 6-7).

Naturally, a plurality of approaches to, ideas about and analyses of particular issues related to research using tissue has always existed. Ethical, legal, cultural and sociological analysis of human tissue is one input into the public discussion of and a contribution to the construction of governance of human tissue research at any given time. But such conceptions are also the outcome of governance structures and the processes that construct them. Particular approaches to governance create a breathing space for some ideas and cut off the oxygen for others. Connected to this, through engagement with the political and policy process, the issues, ideas and questions addressed by the range of interested parties – the inputs, to view the process (wrongly) in linear terms – have in fact in part been framed by these ongoing processes.

Ian Kennedy, Chair of the Bristol Inquiry, had a long-standing and prior commitment to bringing about change in the culture and governance of medical research and practice. In his 1980 Reith lectures and in the book that followed in 1981, *The Unmasking of Medicine*, he drew on Foucault and Ivan Illich in particular in making his argument that medicine is a deeply political enterprise with power concentrated in the hands of the medical profession, to the detriment of patients and the wider public: ‘the nature of modern medicine’, he argued, ‘makes it positively deleterious to the health and well-being of the population’ (Kennedy, 1981, p. 26). Medical research, he added, ‘exerts a spell over governments and foundations and thus over the public’ (Kennedy, 1981, p. 38).

In his view, one of the problems with research is that it presents us with a series of *faits accomplis*: 'It is not a question of whether such and such research ought to continue, or to be put into practical application. It has become a matter of how we adapt to this development. The medical scientist and technologist has won the day.' (Kennedy, 1981, p. 120). He saw it as his task to try to shatter the authority of the medical profession. A key means was through mobilising the emerging idea of consumerism in health.

Undoubtedly, one use of the idea of patient and public participation has been to challenge the power and autonomy of the medical and medical research professions. However, importantly, while some campaigners and influential individuals such as Kennedy have pursued a critique for many years, it was when Government created a political and policy space for such ideas that pressure was really brought to bear. Simon Denegri, Director of the voluntary organisation the Association of Medical Research Charities, poses it bluntly:

'The Government had regulatory choices, but their political choices were very different. So if we go back to that time, the patient choice agenda was very hot off the press. The whole thing about giving patients choices, about empowering patients, had really surged up the agenda. So that was driving things. I think Milburn was completely freaked out by the stories behind the stories of what had happened. There was a pretty overt agenda

at the time about wanting to smash the professions and the hold the professions had over the health service. So there were probably lots of political reasons for why they rammed it quite hard, well, very hard, from the outset. And there were very strong advocates for the patient voice within the Department – such as Harry Cayton and Claire Rayner; these were people New Labour trusted from its very first days in office and had built strong relationships with, who were on the rise as compared with some of the clinical leaders.’ (Interview, Denegri, April 2011)

In the literature and in my interviews with research scientists, it is Michael Redfern, Chair of the Royal Liverpool Children’s Inquiry and politicians, in particular Alan Milburn, Secretary of State for Health at the time, who received the strongest criticism, rather than Ian Kennedy or others. They are seen to have created the space in which untoward ideas and approaches could gain an influence on law and policy at the highest levels, or indeed to have directly caused this to happen. The scientists believe that attention was directed towards those who were aggrieved, that particular responses among these individuals and groups were also encouraged over others, and that this was the background against which the governance of all tissue, not just particular kinds of tissue from particular groups (specifically whole organs from dead children), was recast.



So while, as I have argued and will argue further in 5.3, a number of principles drawn from human rights thinking and law, and other ideas developed by critical social theorists were important, it was the framing of the debate by Government through a focus on emotionally and politically powerful questions that created the political space and leverage for critical ideas and proposals. For Margot Brazier, Chair of the Retained Organs Commission, this was in large part appropriate. Indeed, for Brazier, precautionary and participatory thinking was vitally important given what had happened. We should, she believes, extend our understanding of the law of negligence in relation to psychiatric injury by erring on the side of protecting people from actions that may so injure them: 'The knowledge which we now share about the impact organ retention has had on bereaved relatives must begin to build a case that families are entitled to be protected from conduct which may injure them.' (Brazier, 2002, p. 567). But even Brazier, no supporter of past research practice, agrees, in part at least, with the scientists' complaint that Government elicited certain responses and in a sense went too far:

'I think the Redfern Report is an interesting document. It's written in a highly emotional style. The Bristol Report and The Isaacs Report – which covers a highly emotional issue – are not. Because of that, first of all at a very basic level, it got a lot of publicity. I'm sure the Bristol Report was reported in the Bristol Evening News, but it wasn't as good copy. I think the very passion that those who wrote the report obviously had

themselves then fuelled the expectations of families in Liverpool.’

(Interview, Brazier, July 2010).

Milburn, in statements to the press and Parliament, famously said, after reading the Redfern Report, that it was the most shocking thing he’d ever read. This fuelled reaction further and deeply dismayed scientists. Brazier again:

‘That’s just rubbish. I mean he’d read the Shipman Report. I sympathise with the scientists who found that statement difficult to understand. I think the Redfern Report was shocking. It did reveal practices that showed disrespect, abysmal treatment of people as people, but Harold Shipman killed nearly 300 of his patients. Again I think that Milburn’s reaction gave rise to very high expectations, which were always going to be difficult to fulfil.’ (Interview, Brazier, July 2010).

To retrace our steps slightly, having established the centrality of the idea of patient involvement and choice, and the central role played by Milburn and Redfern, consider the literal issue: is this what patients and the public wanted, and if the Government’s approach was supported by individual patients and patient groups involved in decision-making, how representative were they? That the Human Tissue Authority has members from some patient groups as well as from other non-medical organisations is neither here nor there at one level. Were

these individuals voted on with a clear mandate, and if so by whom? Are they better considered as special interest groups pursuing their own agendas? Or, perhaps the lay members of the Tissue Authority could be considered as carefully selected allies of New Labour and the NHS bureaucracy?

However one views the route by which they came to be on the HTA, the lay views that attained prominence and came to be represented institutionally tended to reinforce New Labour's perspective that the professions needed putting in their place. This still begs the literal question though: was there a great demand for patient choice or patient involvement among patients? We might, crudely, distinguish between particular groups of patients on the one hand and the broader public on the other, and particularly emotive types of tissue and organs in particular contexts on the one hand and tissue in general on the other. The reality is that empirical research is thin on the ground on such issues, but there seems to be a consensus that the public 'in general' and even those members of the public who were concerned about particular kinds of tissue in particular contexts – most notably parents whose children had died and whose organs had been retained at Alder Hey hospital – were unconcerned or little concerned about the wider governance of human tissue about which social scientists have written about and over which the Government initiated action. Those involved in restructuring governance, from all the perspectives on the core issue of retained

organs from dead children, are agreed on this. Peter Furness, President of the Royal College of Pathologists, puts it like this:

'When the Act was being developed I went to quite a few meetings and met the parents of children who were involved in Alder Hey and Bristol, and obviously there was much emotional discussion of human tissue. But I took the trouble of asking those parents that I met "when you talk about human tissue do you mean just post-mortem tissue or are you including biopsies, surgical resections and samples taken from the living?" Every one of them said to me "no, no, just post-mortem tissue." And yet, through absolute rigid insistence by the Department of Health in England, the Act came out covering the whole of human tissue with a definition of human tissue that actually includes not only blood, but urine, spit, you name it; anything that contains human cells. That is not, explicitly not, what the people involved, the parents at Alder Hey and Bristol wanted, and yet that's what we got, and I never understood that. Most research using human tissue uses tissue from the living. I still see no significant benefit in what the Human Tissue Authority does in covering that area, and I see lots of disadvantages.' (Interview, Furness, March 2010).

Margot Brazier agrees on the specific point. When she suggested to a group of aggrieved parents that they might be concerned about tissue taken at surgery

from the living ('waste' material'), she was told that she was 'taking the Mick' (Interview, Brazier, July 2010).

Turning, or returning, to the specific issue of particular kinds of tissue and particular patient groups, it would be a mistake to regard sentiment expressed by some groups as typical of all of those with ill children or whose children had died in hospital. Dixon-Woods and colleagues argue that other groups' attitudes are better captured by Rose and Novas' notion of 'biological citizens' working in close collaboration with professionals:

'The childhood cancer community described by participants in our study includes a collectivity formed around a biological conception of a shared identity, in the form of the family members who identify themselves as "biological citizens" in the sense proposed by Rose and Novas (2005). But the community, as perceived by these family members, extends well beyond the confines of the biological collectivity to also include health professionals and scientists involved in childhood cancer. The interests of the community—improvements in the diagnosis and treatment of childhood cancer, and participation in the 'political economy of hope' (Novas, 2006)—were thus felt to be the same for all members of the community, whether patients, families, professionals or researchers.' (Dixon-Woods, Wilson, Jackson, Cavers and Pritchard-Jones, 2008, p. 72).

So where did the broad regulatory impulse come from? For Sheila McLean, an academic lawyer who was also Chair of the Scottish Independent Review Group on the Retention of Organs at Post Mortem, in the early stages of the debates the Government thought things through to an extent, but was also largely reactive over Bristol and Alder Hey and what should be done. The media storm and very fact that the Government had organised inquiries then reinforced a 'something must be done' mentality. Later, in her view, a lot more thinking and deliberation went into modifying the proposals to take account of the concerns of the medical profession:

'I think it was thought out to an extent. I think it was thought out from the starting point that whatever else they did they had to get consent into this. That was partly I think because of the ferocious media storm that arose around it as well as the high profile cases, and the fact that they'd invested gigantic sums of money, in England at least, in two full-scale enquiries. The only constant that came out of these inquiries was that people should have been asked for their consent. So I think at that point there was no other option. There was no way the Government was going to say anything else. But having done that they then did try to respond to the interests of the medical community and the scientific community, which in my view were grossly exaggerated in any case and not always particularly

relevant. So, to that extent the Government had thought it through, but I think it thought it through from the wrong position.’ (Interview, McLean, March 2010).

However, as discussed and argued above, another reading of events is that Government did much to encourage the media storm. It was keen to be seen to be doing something about perceived public concern, but this was concern it had helped to create. It then took the opportunity to outline proposals for reform of governance that went far beyond the immediate issue of retained organs. Redfern had not considered this wider agenda; that was not in the Committee’s remit. The motivation for this wider reform came from within Government, more specifically from the Chief Medical officer and his team. Hugh Whittall, the lead civil servant at the time, argues that Government took hold of ideas that were in the air, as well as rhetorical statements made by the General Medical Council, the Medical Research Council and others, and turned them into a reality:

‘There was not a kind of lobby group; there was not a big groundswell of opinion. I don’t think there was a sense of something about to erupt. But rather I think it was that there was a feeling that we were part of a shift in the relationship between individuals and health services. At the time the language of choice and partnership were very, very much what the political environment was about: about patient choice, about patient

partnership, about engagement, about non-paternalistic approaches to medicine and healthcare. And so I think this was very much kind of catching that wave and believing that to make assumptions about what people might think is OK, or to make assumptions that “because we’re doctors and we’re doing good things everybody will be happy with it” was no longer acceptable as a basis for a practice. Starting afresh you would say, no, bits of people’s bodies, the starting point is them, and so I think that it was not that there was a body of dissatisfied opinion growing out in the public, but rather that this would help to maintain that change in a much wider culture of how we relate to not just health services but health sciences....

...I hadn’t thought about it before but I do just want to come back to emphasise again this point, which is that despite all of that, and despite what seems to be the evidence that researchers find the current conditions difficult, I do think that this reminder is important, the reminder that all the previous guidance was as restrictive. It just was ignored. That was part of the background. We could not continue in a situation whereby researchers were continually in breach of GMC guidelines. That was just untenable. And MRC guidelines.’ (Interview, Whittall, May 2010).

The way forward was outlined in the CMO’s response to Redfern in January 2001. Eighteen months later, the consultation *Human Bodies, Human Choices*



expanded on this wider agenda. This was a key turning point in the debates. It was now very clear to the medical profession that wide ranging legislative reform would take place, on a basis they found quite shocking.

My own analysis of the responses to *Human Bodies, Human Choices* (which are retained by the Department of Health and to which I was granted access) is that out of 231 Responses the majority could be described as neutral, though this is not straightforward. Some in this class consisted of a brief note on a particular aspect. The brevity or specificity could be taken in more than one way: for example as supportive of the broad thrust of the document or alternatively as a resigned acceptance of the broad thrust. That the brief mention of a particular aspect was often a defence of past practice could be taken to imply that the author of the note was critical of the thrust of the consultation document, or it could be taken to mean that they thought it was OK on the whole, but needed correcting on a small point. It is hard to be sure.

What is clearer is that around 50 were supportive of the proposals put forward by Government. Of these, some came from professional organisations, such as transplant societies, but the majority came from individuals, many of them members of the public, a good number of whom had a direct connection to the issue. Some if not many of these were very brief indeed; for example handwritten comments on a leaflet issued by the Department at a meeting it organised

in Liverpool. What is also clearer is that around 40 were clearly critical of the proposals put forward by Government. Of these, the majority came from professionals or professional organisations, pathologists in particular, but not entirely so.

The document *Summary of responses to the consultation report*, in other words the document in which the Government (specifically the Department of Health) considered the responses to *Human Bodies*, *Human Choices*, followed the original document closely in terms of the main themes and proposals. Moreover, it argued that the majority of or even all respondents agreed with the original document on most or all issues, including the need for a system of strict consent and a system of criminal penalties. Regarding the latter, it stated: 'the response to the consultation suggests broad support for the approach in *Human Bodies*, *Human Choices*... imprisonment should be included as the most serious penalty... the new systems being proposed should 'enable, not hinder, education, training and research.' (Department of Health, 2003, pp. 9, 16, 24)

As the Government was soon to discover when it carried these proposals over into the Human Tissue Bill, published in December 2003, this support was not as broad as suggested. But in reality, it was never really there in the responses. It seems highly unlikely that the Government was unaware of this. It is not simply

that 40 of the responses were critical; some if not all of them were clearly so.

Consider the following extracts from Cancer Research UK's submission:

'The report [*HB, HC*] is written within a framework based on concepts and principles. However, it fails almost completely to define unambiguous, practical guidelines for dealing with any real situation...

... The report appears to threaten both extensive regulation and significant penalties for "responsible individuals" if these regulations are not observed. While Cancer Research UK believes that everyone would support severe penalties for individuals who deliberately set out to flout agreed regulations, the suggestion of penalties for inadvertent lack of compliance is misconceived and likely to be very damaging...

... The question (example 2, p. 181) about penalties for a technician who used pathology slides for teaching when there had been consent only for research is another, extraordinary, comment on the mind-set that apparently some people have reached. What possible importance could there be in a distinction between anonymous sections from a pathology lab being used for teaching rather than research... think of the bureaucracy needed to ensure that all the tens of thousands of samples in a pathology department were clearly labelled to indicate what was permitted. And to what conceivable end?...

... The discussion (section 9, 37, 9-40) [question 9k] about disposal of human tissue seems another example of marginal concerns obscuring some real issues. Can it really be helpful to spend time debating whether “disposal” is a suitable term? Do we really need a discussion about “respectful disposal” of tissue removal (sic) at operation? Blood soaked swabs to be given a decent burial?’

This response, while strongly put in places, was far from being exceptional. Another theme in some critical responses to *HB*, *HC* was that the powerful emotional response of a small group was unrepresentative and threatened the interests of the vast majority. In his response Peter Furness reported on a survey that found that 99% of over 2000 patients surveyed were happy for waste from surgery to be used in research, even if this involved transfer of tissue to a commercial organisation.

The simple and obvious interpretation is that Government was attempting to pursue change in the face of a confused and somewhat hostile, if also slightly cowed, medical profession. CRUK’s submission was direct and to the point. Not all critical responses were so clear. That some of the more gentle or gently put criticisms were also ignored was to store up problems for later. Of particular note is the submission from the Medical Research Council. As discussed above, Hugh Whittall argues that the Government, in the Human Tissue Bill, was in effect

holding the research community to, among other things, MRC guidelines. There is something in this, and for some other organisations the MRC guidelines were problematic for just this reason – CRUK described them as ‘unhelpfully burdensome’ and argued that ‘the zeal to explain every nuance of what would happen to a sample was perceived [by researchers] to lead to a consent process that was threatening, difficult to understand, and discouraging to the research participant.’ But the Government not only endorsed the MRC’s guidelines, it firmed them up, interpreting them in a particularly rigid and simplistic way. In its submission to *Human Bodies, Human Choices*, the MRC pointedly noted:

‘The Council welcomes the endorsement of its own Guidelines in this paragraph. There is one difference, though. The Consultation states: “Patients should be asked whether organs or tissue left over following diagnosis or treatment may be retained and/or used for research”. The MRC guidelines state: “Patients should always be informed when material left over following diagnosis or treatment (described as surplus to clinical requirements) might be used for research. Wherever practicable, and always when the results of research could affect the patient’s interests, consent should be obtained to the use of such surplus material.” We continue to prefer the wording in our own Guidelines.’

The more complicated explanation is that Government was subjectively and in many ways practically very much in favour of aspects of, if not much of, medical research and practice. It was, for example, around the same period, re-organising cancer services and research in a way that included a particular enthusiasm for clinical research and an injection of extra money. Of a piece with enthusiasm for research and in tune with its centralising tendencies, New Labour was keen to promote a system of consent for researchers working with larger, organised, collections of material for research: biobanks. A number of leading researchers and professional bodies were closely involved in developing these initiatives and new structures.

The Government thought it was, or found it easy to believe that it was, possible to promote both medical research and an agenda of patient choice and participation that drew upon aspects of the Democratic Model. Keen to receive the extra money and to work with Government, and not known for overt campaigning, some of the august medical bodies failed on the whole to communicate their concerns about the direction of travel around tissue in a way that would make Government and civil servants sit up and take notice, until, that is, they felt they had no choice following the publication of the Bill.

### 5.3 The Human Tissue Act and human tissue research

In this section the changes from the Bill to the Act, the role of the Human Tissue Act within the wider nexus of research governance systems and the consequences for research are examined. In some ways the outcome has left no one satisfied, at least none of those with a keen interest in radical change on the one hand and supporters of old systems of research practice on the other. But while the dissatisfaction of proponents of change suggests that the medical profession did recapture some lost ground during the Parliamentary debates, it does not, I argue, show that the profession achieved anything like a return to the situation prevailing prior to the controversy around Alder Hey. Change is real and in part at least harmful to research practice.

David Price was an academic lawyer who argued that human rights principles should, indeed must in some way, apply to the use of human tissue in research. He nuanced this with the argument that consent is always propositional and context specific. But when it came to who should have the power to decide what happens to tissue, Price was clear: the most important thing was that the individual patient or member of the public has the authority to decide and should have the opportunity to do so. He was sympathetic to the idea of individual property rights or at the very least favoured a rights-based framework with similar powers:

'An overarching legal and ethical framework is essential. A rights-based framework set against a dignitarian baseline reflects the most appropriate skeletal regulatory model, with individuals themselves having *prima facie* authority and control over materials emanating from their own bodies, best captured in the notion of property rights and donation in terms of (conditional) gifts. Such rights attach even to the use of one's corpse after death, and reflect posthumous interests deserving of protection.' (Price, 2009, p. 283)

For Price and others the core issue is simple and should not be controversial: it is about asking people for their permission; it is a basic issue of respect for the individual. The Government made these and similar arguments during the passage of the Human Tissue Bill through Parliament. Indeed, the 'Golden Thread' running through the Human Tissue Bill was consent. Sheila McLean believes that 'people are no longer prepared to be the passive recipients of medical beneficence or to have themselves or their families treated merely as the "subjects" of research.' (Campbell, McLean, Gutridge and Harper, 2008, p. 108). She argues forcefully that human rights provide the bedrock-principles that must govern research of whatever kind. For McLean, the reaction to Alder Hey was driven not primarily, or not simply, by powerful emotion linked to the death of children and the taking of whole organs, but rather by the lack of respect shown



by the taking of the organs, an attitude that in her opinion extended across all research using human tissue, from whatever source, whether from the living or the dead, whether large or small, whether identifiable or anonymised: 'I don't think they [researchers] can presume to know what is important to people and what people's feelings are about anything, however small it might be.' (Interview, McLean, March 2010).

Natural scientists, especially in the final stages of the Parliamentary process, pressed hard to amend the Bill, so as to, in relation to the specific issue of consent, break the Golden Thread. In part they were successful. Under the terms of the Act, it is possible to use anonymised tissue without consent, if a Research Ethics Committee grants approval. Natural scientists and their allies did not however manage to defend the possibility of using *identifiable* tissue without consent in particular circumstances, and nor did they manage to escape from what they regarded as the trap of consent and regulatory requirements that bore little relationship to real practice or the real concerns of most patients.

Nevertheless, that researchers managed to remove the need for consent in some circumstances when using anonymised material and more broadly that Government Ministers made a number of 'pro research' statements during the final stages of the Parliamentary process has led McLean and a number of legal and social science analysts to the conclusion that the influence of privacy rights

and concerns about commodification on the final Act are fairly weak, and that in reality it is largely business as usual.

For example, reflecting on the changes that have occurred in legislation and governance more broadly, the problem for academic lawyer Jean McHale is precisely that anonymisation is allowed in some circumstances as a tool of research, because this subverts what she sees as the key principle of individual control, rights and participation in research and may indeed be dubious, on legal grounds. Broad change is needed, she concludes, 'before we are forced to by another crisis or scandal such as Alder Hey.' (McHale, 2011, p. 245). Or consider legal scholar Roger Brownsword's overall assessment. As discussed in chapter four, in his *Rights, Regulation, and the Technological Revolution*, he examines how the utilitarian, the rights and the dignitarian perspectives use and regard key concepts, especially consent, harm and precaution (Brownsword, 2008).

Brownsword's analysis, which he applies to human tissue governance as well as human embryology governance among other areas, is that utilitarianism, with some ethical and political limits, is the default position. Regarding the Human Tissue Act, he argues that:

'Although consent has been proclaimed as the cornerstone of the UK human tissue legislation, the underlying rationale is essentially utilitarian.

Thus, according to a House of Commons Research Paper (No 04/04 on

the Human Tissue Bill), the government believes that the effect of the consent provisions will be to “prevent a recurrence of the distress caused by retention of tissue and organs without proper consent”, to “help improve public confidence so that people will be more willing to agree to valuable uses of tissues and organs” (such as for research and transplantation purposes) and to “improve professional confidence so that properly authorized supplies of tissue for research, education and transplantation can be maintained and improved” (p 4).’ (Brownsword, 2010, p. 26)

Specifically on privacy and consent, for Shawn Harmon and Graeme Laurie, the protection of privacy that is enshrined in Article 8 of the Human Rights Act (HRA) 1998 is a basic legal fact that has to apply in some form but that need not and should not have particularly negative consequences for research. Like many of the rights protected by the HRA 1998, the application of Article 8 is a balance between 8(1), a clause that sets out the basic principle of protection of private and family life, and 8(2) that sets out qualifications to that principle. What is more, and again typically, the application of the law is context specific and subject to interpretation. For Laurie the influence of this legal framework has not led to a strong or powerful protection of individual control rights in the Human Tissue Act. If it had, he argues, the Act would recognise an intrinsic individual property right, whereas in fact it rejects this idea in favour of the idea that professionals can

create a property right for themselves over the patient's tissue through working on it (Harmon and Laurie, 2010, and Laurie; personal communication).

Certainly then, for critics of the pre-mid-1990s position, the usual conclusion is that changes to the governance of human tissue research are neither as extensive nor as negative for research as some natural scientists claim. What is more, some think many natural scientists are coming around to realising that this latter point is a correct and fair assessment. It is quite possible, likely in fact in McLean's view, that we hear from the disgruntled, pathologists in particular, more than we do from the contented. McLean believes that changes are taking place in the attitudes of researchers, and that outside of the pathology community the Human Tissue Act can be, and often is seen to be by the researchers themselves, helpful for their work. This is based on a fairly robust view of the need for change in practice, as we have seen above, but nevertheless she also thinks that the profession is not as hostile as is often made out. To the extent to which there continues to be resistance to new ways of thinking, and new ways of working in so far as there has been change, from within the research community more broadly, this is perhaps best explained by generational issues:

'There's a whole new generation of doctors who are being educated differently, and scientists, who are being educated to integrate ethical and legal values in their education and so they don't see themselves as just

being stand alone, isolated from their community, people who can do what they want because they have this special expertise. So, I think these kind of objections would have faded anyway as older generations of people left the business.’ (Interview, McLean, March 2010).

In the subsections that follow I challenge the interpretations of McLean, Brownsword, Laurie and McHale. Building on the arguments of sections 5.1 and 5.2, and drawing on Gillott (2006), interview material and an assessment of survey data, I argue that change is substantive and has been damaging to research interests.

### **5.3.1 Governance, research, rights and consent**

The first and most general issue to highlight is the way in which research more than other activities was subject to particular, and critical, scrutiny. Brownsword’s suggestion that the focus on consent was largely formal and that the main concern of Government was the utilitarian one of promoting research fails to take account of the substantive implications of consent provisions not just in the Bill but also in the Act and the wider governance context of which it is a part.

At a general level Dixon-Woods and Ashcroft note that, as far as the research community is concerned it is the designation of an activity as research that is today critical to how it is controlled, not ‘the inherent “riskiness” of the activity.’ It

is the social characterisation of the activity and, crucially, the range of institutional arrangements that follow from this that is the cause of the difficulties for researchers: 'The institutional risk (the one that requires the institution to be able to make displays of the robustness of its systems) takes priority over the risks to society. The social policing of ethics and governance itself reinforces this tendency... the practical consequence for researchers is that procedural compliance with regulatory requirements is inescapable.' (Dixon-Woods and Ashcroft, 2008, p. 387).

Research using human tissue is isolated in this way in the Human Tissue Act. In broad summary, unlike other professional activities, such as audit or the sharing of information for clinical purposes, the activity of research using human tissue is considered as something apart and something especially invasive. In the Bill any research use of tissue, whether anonymised or not, would have required consent. In the Act anonymisation can be used instead in some circumstances. But the default expectation is that consent should be gained. Furthermore, it is consent of a particular kind. David Price, unlike some other academic lawyers with an interest in this area, proposed that a system of tacit or implied consent should be used more widely in the research context. Many clinical researchers think this is how things worked in the past and it is how they would like things to work in the present. However, Price recognised that this is not in fact how others see it, and crucially not how the drafters of the Bill and the Government intended it – it is not

made explicit in the Act, but it is widely thought that the Human Tissue Act is based on a system of explicit consent, insofar as particular activities under the Act require consent, which in turn reflects the political context of the Act's gestation (Interview, Price, July 2010).

In a little more detail (see Gillott, 2006, for a fuller discussion), the original Bill proposed that all research required consent. However, before entering the Lords, changes were made and clarifications given in response to severe criticism from what Lord Warner later called the 'medical-scientific establishment':

'Following extensive discussion with a range of medical research interests, including many eminent people in that sphere, amendments were also made in another place to provide for the use, without consent, of residual tissue from living patients in research, provided that the tissue is effectively anonymised and the research approved by a research ethics committee.'  
(*Lords Hansard*, 22 July 2004, columns 369-70).

The HT Act lists, in Schedule 1, Part 1, purposes requiring consent. Included in the list is: '6. *Research in connection with disorders, or the functioning, of the human body.*' This is an extension and elucidation of general principles outlined at the very beginning of the Act, in Part 1. However, in Part 1 of the Act we also find that sub-sections 1(7)-(9) provide:

'(7) Subsection (1)(d) does not apply to the storage of relevant material for use for the purpose of research in connection with disorders, or the functioning, of the human body if-

- (a) the material has come from the body of a living person, and
- (b) the research falls within subsection (9).

(8) Subsection (1)(f) does not apply to the use of relevant material for the purpose of research in connection with disorders, or the functioning, of the human body if-

- (a) the material has come from the body of a living person, and
- (b) the research falls within subsection (9).

(9) Research falls within this subsection if-

- (a) it is ethically approved in accordance with regulations made by the Secretary of State, and
- (b) it is to be, or is, carried out in circumstances such that the person carrying it out is not in possession, and not likely to come into possession, of information from which the person from whose body the material has come can be identified.'

A similar couplet—stating the general principle of consent then excluding



anonymised samples—governs genetic analysis (Part 3, 45 & Schedule 4, Part 2: 10). Uncertainty remains as to the circumstances in which it is expected that consent should be sought rather than relying on anonymisation. Lord Warner's statement in the first Lords debate—on the possibility of research without consent using anonymised samples—was repeated several times by the government in response to probing by Peers. However, save reiterating that RECs would consider the issue, statements in the debates on this question always contained an element of ambiguity as to the circumstances in which consent should be sought.

Statements also contained an element of ambiguity as to whether and when consent could be broad or general, and when it should be more specific. For the government Lord Warner, in the first Lords debate, upheld the validity of generic and enduring consent in the following terms:

'The Bill does not set out the form consent should take in any particular situation. Let me state clearly that the Bill does not require consent to be specific to each research project for which tissue might be used. Consent can be broad. Consent to research can be generic and enduring.' (*Lords Hansard*, 22 July 2004, columns 369-70).

This same point had been made by the government in the Commons debate and

was repeated several times subsequently. In the Lords debate at Report stage, Onora O'Neill (Baroness O'Neill in this context), along with many other knowledgeable members of the Lords, welcomed such Ministerial comments. She supported (unsuccessful) attempts to have this inserted into the Bill. Earl Howe explained the keenness to see the statements written into law:

'... worries persist. They persist principally because of the requirement for specificity of consent laid down by many research ethics committees. They also stem from the fact that the Bill is silent on the whole matter. If we are serious about the need to maintain the momentum of medical research in this country, and about imposing on it the least possible administrative burden, there is a case for ensuring on the face of the Bill that obtaining generic and enduring consent will be one option open to medical researchers when presenting their proposals to research ethics committees for approval. A signal of that kind would be important for the HTA.'*(Lords Hansard, 15 September 2004, column GC 517).*

This illustrates the sometimes-perplexing character of the regulatory regime facing researchers at the moment. The government argues that generic and enduring consent is valid. The government also states that they cannot second-guess the decisions of Research Ethics Committees, to whom they are looking to make the decisions in practice. At the same time RECs often insist on specific

and time-limited consent. They in turn look for guidance, but receive little from the government beyond general statements. Researchers find themselves caught in the middle, and increasingly feel themselves to be knocked from pillar to post.

In addition to pressing for amendments to legitimise generic and enduring consent, Baroness O'Neill and Earl Howe also pressed the Government to accept amendments that would have allowed research using identifiable tissue without consent subject to appropriate ethical approval. The attempt to amend the Bill in ways that might appear to be contradictory—reinforcing the legitimacy of general consent and simultaneously seeking a mechanism for the confidential handling of identifiable tissue without consent—further illustrates the complexity of the issue. At the heart of the problem is the tension between the pressures of clinical practice and the complexity and open-ended character of research on the one hand, and the ideal of express and informed consent on the other. No matter how often the government states that generic consent is valid, the concern remains that in specific circumstances it might be thought insufficient.

So, in summary on research and consent, while apparently simple, in fact it is in practice not always at all simple to satisfy consent requirements, or to know in advance what will count as satisfactory consent. Sometimes it is very hard even to set about gaining explicit consent, especially if someone else has already collected the material. All in all, typically it is not direct prohibitions that are the

main cause for concern so much as a collection of principles and structures that are difficult to negotiate. Ambiguity, which in less restrictive governance structures can be positive for research, is at best a mixed blessing for tissue researchers: to this day projects founder because it is unclear as to whether they are service development or research (Cronin, Rose, Dark and Douglas, 2011). Some even find it difficult to publish results for similar reasons (Sebire and Dixon-Woods, 2007).

### **5.3.2 Waste and consent**

The second issue to highlight is the basic or background one that many if not most people, even those concerned about the original issues thrown up by Alder Hey, think asking about consent to the use of waste material is, as Peter Furness argues, 'not, explicitly not', what they were concerned about. In the narrative of those advocating change this is not considered relevant, or is passed over to an extent. So, McHale may believe that anonymisation of any kind of tissue followed by research on it without consent risks a repeat of the Alder Hey scandal.

McLean may believe that not asking to examine a urine sample or a piece of waste surgical tissue and not asking to retain and examine a dead child's heart both reflect an underlying lack of respect for people. But the reality is that these were neither the concerns of most of those involved in Alder Hey nor the concerns of the public more broadly, in so far as we know anything about their views.

Nevertheless, focusing on Alder Hey, rather than McHale's fears about a new one, governance arrangements were put in place to cover all kinds of tissue. Implicitly or explicitly, many of the proposals and changes relied on Democratic Model ideas and precautionary thinking about public opinion and concerns, as well as the dangers inherent in professional practice. The issue, in other words, is as much about starting points as finishing points: the very fact that waste material was drawn into an explicit governance structure represented a powerful shift in research governance. It was a basic aspect of the way in which research was isolated within governance, as discussed above in 5.3.1, and a significant contributor to the complexity also discussed in 5.3.1.

Of course the way in which waste material was included in the final Act might not have created a clear and firm right of individual control, still less, as Laurie rightly points out, an intrinsic individual property right. But just because the change wasn't startling doesn't mean it isn't significant (for a critical examination of what a property right might mean, see Dixon-Woods, Cavers, Jackson, Young, Forster, Heney and Pritchard-Jones, 2008, p. 144). Or, put another way, just because control wasn't handed completely and clearly to the individual patient does not negate the fact that Government enactment of participation took away some control from the professions.

That some control has been taken away is clear to researchers and a source of some anger. In today's world of research there is much to be gained by linking multiple data and tissue collections. Anonymisation is possible, but to link the different sets someone needs to be able to return the data and samples to a non-anonymised form, even if only temporarily. The idea that 'Trusted Third Parties', perhaps collected together as a formal or quasi-government agency, should handle the necessary anonymisation and de-anonymisation required carries with it the obvious message that such parties are more trustworthy than researchers. This message reinforced the irritation, and even hostility, of many scientists. In debate on the Tissue Bill Lord Winston made the pointed observation that: 'there is a deep mistrust of politicians rather than a mistrust of the medical profession. As every review reports, scientists and doctors are much more trusted than politicians. Noble Lords ought to bear that in mind when we consider these matters and seek to put them in some kind of focus.' (*Lords Hansard*, 22 July 2004, column 385).

### **5.3.3 Consequences for research: scientists' views**

The third point to highlight is the breadth and depth of frustration amongst researchers, especially those researchers not working on specific projects linked to well-organised samples of tissue. Sheila McLean, as we saw above, thinks it is mainly the older generation, and pathologists in particular, who are unhappy. However, John Burn, a clinical geneticist rather than a pathologist, and not quite

so old as to need to leave the business for some while yet, concluded my interview with him on a critical note about a number of regulatory structures, those governing human tissue research in particular:

‘One of the downsides of the British system is that they do create these most elaborate [regulatory] structures, the most dramatic of which is the Human Tissue Authority, which has grown out of that mad Dutchman in Liverpool and a misinterpretation of the Bristol inquiry. We get a knee-jerk response from a few politicians and suddenly we’ve got a Royal Commission and suddenly we’ve got a Human Tissue Authority. We’re being searched; every office in the NHS was searched for body parts at the height of that nonsense. And now we’ve got this huge, elaborate employer of people who come round and inspect all our processes for handling tissue samples. They charge us thousands upon thousands of pounds for our licence. If it all went away nothing would happen. It’s just a process to make somebody feel better.’ (Interview, Burn, July 2008).

Importantly, it is not just the Human Tissue Act that needs to be considered in this context. As researcher Richard Sullivan (another relatively youthful non-pathologist) argued in interview:

‘Overarching this, you’ve got to remember that a researcher is not just hit by tissue legislation. There’s been a huge increase in governance: at local level, NHS Trusts, in universities, and then there are the forms people now have to send: internal review processes, Clinical Trials Directive, data protection legislation despite Section 60 and tissue. There is this magnifying effect. The governance environment now for research is highly oppressive, I would argue. We’ve over-regulated the system, and that’s been a fault of the research funders, it’s been a fault of Government and it’s been a fault of the host institutions, both the NHS and the universities, and they’ve all fed into each other; there’s very little coherence. There have been attempts to get coherence in various areas, research ethics committees etc, but the overall weight of what you have to do now is huge.’ (Interview, Sullivan, April 2010).

But beyond individual opinions, what do we know about the views of researchers, and what do these tell us about the consequences of governance for research? onCore UK (2009), and the HTA itself (2009) have conducted surveys. The HTA has also commissioned surveys of researchers (one of which is Ipsos Mori, 2010), to assess researchers’ views on research governance. The trigger for these was a sense that researchers were unhappy about a number of issues, and the surveys do indeed bring this out. At a general level, respondents found it hard to separate issues arising from specific governance structures for tissue



research from issues arising from the complexity of governance in general.

Typically, the multiple forms of governance under which they work, including the HT Act and the HTA, Research Ethics Committees, NHS R & D structures and hospital governance arrangements (if applicable), were highlighted as the most frustrating thing. Many hoped the overall system could be simplified. At a pragmatic level, or as a second best, what many wanted was a clear guide to the system – something and someone to lead them through it (onCore UK, 2009).

Regarding tissue governance as such, the striking issue is not so much that researchers have a negative view of how the staff of the HTA go about their work (Ipsos Mori, 2010), though there were criticisms, but more that they disagreed with the HTA's claims that the law and regulatory bodies have made a positive contribution to research practice. On the whole, researchers took and take the opposite view, with those working in the NHS and pathologists in general being the most critical; (by contrast those working in biobanks were more positive). Overall, only 20% of respondents thought that regulation and governance did not hold up research unnecessarily. When asked to comment specifically on human tissue legislation and its required implementation by the HTA, the majority of participants thought that 'human tissue legislation and subsequent regulation by the HTA had a negative impact on the sector.' The key overall statistics were: 59% thought the overall impact was negative; 26% thought it positive; while the rest were undecided (HTA, 2009).

As I noted in chapter three (section 3.4), care is needed in interpreting results and findings. James Ironside, a leading researcher into vCJD in particular and human brains and related tissue in general, is less critical than Burn and Sullivan of the Human Tissue Authority and some other governance structures. More than this, he is critical of his colleagues, especially the older and more senior ones, who he believes have encouraged the spread of unreasonably negative perceptions about the Act and the Authority:

‘I don’t have a lot of sympathy with those point blank negative judgements. My experience is that there is a substantial body of professional people who were opposed to the Act, the wording of the Act, even after the changes following consultation, and they will never change their minds, I don’t think. And unfortunately what’s happening, I think, is that this negativism is seeping downwards, from the head of the unit to the research teams, and so this negativism is being if you like cultured and disseminated locally. It doesn’t happen everywhere, but it does happen in certain places... I think it’s much easier to find people who are negative. If you’ve been working for years without any perception of regulation and then suddenly this regulatory body is created; it’s telling you what to do, and charging you money for doing it, then you don’t like it. And the idea of penalties is something else that people don’t like. These reactions don’t

encourage younger researchers to view the Act and the Authority in a very positive light.’ (Interview, Ironside, March 2010).

Perhaps, as Ironside suggests, such generational, structural and cultural issues are involved. But such considerations cut both ways. Ironside runs a large brain bank in Edinburgh, Scotland. He has also worked closely with the HTA and Government over the years (he was for a while on the HTA). In general, the research suggests that those who work in, or in close collaboration with, large, organised biobanks of one kind or another and those who work in a leadership position in such bodies in particular, tend to be more supportive of the new governance structures than those who do not. Or more accurately, they tend to be less critical, for in the research undertaken by onCore UK and the Human Tissue Authority, no sub-group contained a majority who saw the impact as positive on the whole. In general, more than half of those working in the NHS classed the impact as being very negative, and bench researchers, the rank and file if you like, were the most critical (HTA, 2009). Interestingly, while the same survey noted that on the plus side more than half of researchers thought that the HTA had raised standards of research processes and tissue storage, ensured donors give informed consent and led to clearer guidance on what can and cannot be done legally, at the same time on the minus side more than half of researchers thought that the Act and the Authority had led to researchers

changing their plans, made it harder to get hold of samples and led to potentially valuable samples being disposed of.

The HTA itself argues: 'The HTA licenses organisations that store human tissue for research. One of our key aims is to ensure that research continues to thrive in the UK. We believe that good regulation supports good science, which in turn leads to improved healthcare.' (HTA website). In interview however, the HTA's Shaun Griffin was prepared to acknowledge that the researchers might be right, but if they were, that was the way it should be:

'A lot of this is my personal view. I do think that that's the way it is. It's very hard for people who've been used to, and I think this is also a generational thing, are used to doing what they want to, to actually change their approach. But I think for me it's doing the right thing: you're using people's tissue and they should be properly informed, and with the notable exception of the exemptions under the Act, I don't think anybody has got the right to take a piece of tissue and do some research on it without somebody's consent. I do feel really strongly about that. OK, it might be more difficult, but it's difficult for a reason. That regulation is there to protect public and professional confidence, and if you don't have this public confidence then you're not going to have people donating. The regulations are there in the public interest and we know that if people know

the regulation is in place then they're more likely to donate. So yes, some people have got concerns about the need to take consent, but it's the right thing to do and it's the will of Parliament.' (Interview, Griffin, May 2011).

#### **5.4 Conclusion: the changing governance of human tissue research**

While some campaigners and influential individuals such as Ian Kennedy have pursued a critique of the medical profession for many years, it was when Government created a political and policy space for such ideas that pressure was really brought to bear. Through highlighting the offence caused to some parents in particular and through the mobilisation of and performance of the idea of patient and public participation in general, Government recast the governance of all tissue. This is why, in the literature and in my interviews with research scientists, Alan Milburn, Secretary of State for Health at the time, is singled out for especially strong criticism.

The Government thought it was, or found it easy to believe that it was, possible to promote medical research at the same time as promoting an agenda of patient choice and participation that drew upon aspects of the Democratic Model. Keen to receive the extra money and work with Government, and not known for overt campaigning, some of the august medical bodies failed on the whole to communicate their concerns about the direction of travel around tissue in a way

that would make Government and civil servants sit up and take notice, until, that is, they felt they had no choice following the publication of the Bill.

In some ways the outcome has left no one satisfied, at least none of those with a keen interest in either radical change on the one hand or supporters of old systems of research practice on the other. But while the dissatisfaction of proponents of change suggests that the medical profession did recapture some lost ground, it did not achieve anything like a return to the situation prevailing prior to the controversy around Alder Hey. Change is real and, as far as one can tell from subjective survey data, at least in part harmful to research practice.

As Manson and O'Neill argue, in the research context, 'nobody has the slightest interest in making facts about any individual known... a great deal of medical (not to mention other) research *uses* information about identifiable individuals for entirely *impersonal* ends... Yet if we think that individuals have a right against others possessing and using their "personal" information, such studies will be seen as breaching that right, and may seem to require consent from each individual whose data are held or processed.' (Manson and O'Neill, 2007, p. 109).

Many scientists have struggled to come to terms with these ideas and changes. Beyond the formal aspect of consent, many natural scientists and doctors believe

that the real content remains a confidential relationship between patient and doctor / scientist, based on trust that professionals are behaving ethically and in the public interest. Part of that trust is an understanding that doctors and scientists will handle sensitive information and tissue in confidence. Approaching the issue from the perspective of anonymisation, scientists wonder why they should invest a lot of time and effort, and maybe lose important information in the process, for little gain, when a system of qualified confidentiality has served them and the public well for many years. And aware in particular that most if not nearly all people have little concern about the use of waste material in particular, natural scientists have struggled to come to terms with the application of privacy arguments and law to research using human tissue and data.

Some researchers have tried to claim or assert a 'right to research', which, correctly from a legal perspective, has failed – as the distinguished legal scholar David Feldman pointedly told The Academy of Medical Sciences: under UK law the question should not be whether there are disproportionate interferences with the capacity to conduct research, but whether research disproportionately interferes with the right to private life (The Academy of Medical Sciences, 2006, p. 7). More fruitfully, working within a rights framework, some researchers advocate a public interest defence to justify limiting privacy claims. This defence is in effect used to support research using anonymised data (it is a defence to claims that the privacy interests that remain after anonymisation should rule out

this kind of research). However, overall, the interaction of the political debate with the creation of regulatory structures that were insensitive to the subtleties of research, including the implicit rules that allowed systems of research to function, led to complex structures and has, to this day, set limits to the practical use of the public interest approach as a means to finesse barriers and maintain or recreate a space for professional discretion.

Roger Brownsword's analysis, that utilitarianism, with some ethical and political limits, is the default position, has obvious appeal. However, the discussion in this chapter suggests that a different reading is more plausible. Taking a more political and sociological approach to the issue, taking account of New Labour's centralising and instrumental approach, one at odds with the inclinations of many on-the-ground researchers, and taking account of the way in which ideas linked to rights and commodification actually play out in the contemporary governance context, leads to a more complex and less 'research friendly' picture.

Of course Brownsword does note the issue of complexity, and indeed the difficulty of addressing it. But it does not occupy too much of his attention because at root his concerns lie elsewhere – in the dangers of amoral governance and an acceleration of scientific research touching on core aspects of human nature. At times Brownsword is prepared to step back from formal statements containing rights based or dignitarian thinking to detect a utilitarian



calculation. At other times he takes formal statements at face value when they proclaim an essentially utilitarian calculation. The result is an overall assessment that is biased towards detecting utilitarian thinking. Brownsword's focus on philosophical ideas and mechanisms of regulation is not sensitive enough to the political context of governance and the social and sociological ideas in play.

As I argued in section 2.8, there is nothing wrong with wanting to change the culture around science or having broader political and cultural ambitions. Many people have such aims and aspirations to one degree or another (in varying directions of course). But there is something deeply unreflexive about some of the critical social science and right-based analysts. They find it hard to put themselves in the picture, to consider their own influence, to consider the way in which they bring or attempt to bring meanings and interpretations to bear on debates and processes, to consider that what from their point of view might be a limited influence amounts to a great deal more from other perspectives.

In a number of recent articles, bioethicist turned bioethicist / sociologist Adam Hedgecoe is critical of his bioethical colleagues for becoming trapped by some natural scientists' framing of the issue in areas of genomics he's interested in (pharmacogenetics, especially). He sees them, like some campaigners, as rolling around the bottom of what Donald MacKenzie dubbed The Certainty Trough:

‘in the case study presented here, the confluence of these three themes – the timing of pharmacogenetics, the internal issues concerning quality in bioethics and regulatory capture – has produced a debate about the ethics of pharmacogenetics that stays within strict boundaries and that serves to support the kinds of expectations being generated about this technology by industry and by academic scientists. Drawing on wider ideas within STS, we can place bioethicists at the bottom of Donald MacKenzie’s “certainty trough”, along with those people “committed to the institutional and research programme” who are not directly involved in research but who may well use, comment on or manage its results; people who have low uncertainty about the technology concerned (MacKenzie, 1990: 372). MacKenzie drew up the certainty trough in an attempt to outline people’s attitudes in his research on nuclear missile guidance systems, and nuclear weapons provide a useful way of thinking about bioethicists and the role they should play with regard to scientists’ expectations and hopes.’ (Hedgecoe, 2010, p. 179).

Some social scientists, focused as they are on pursuing a critique, paid insufficient attention to the subtleties of, and tacit rules guiding, natural science research practice in the areas discussed in this chapter. Like the bioethicists criticised by Hedgecoe, and the campaigners commonly criticised by social scientists, some critical social scientists have also been guilty of bringing a high

degree of certainty to a messy area of practice. Relatedly, at issue is the tension between analysis and commitments (see Jasanoff, 1996, Williams, 2006) and the role of social scientists in the many forms of policy processes and debates, such as, for example, upstream engagement (see Williams, 2006, Tait, 2009, Hedgecoe, 2010). I return to these themes in the concluding chapter of this thesis. But first I consider the second case study, research using human embryos.

## Chapter 6: Engagement, pluralism, deliberation, embryos and research

'We need to be attuned', argues Duncan Wilson in his 'Creating the "ethics industry": Mary Warnock, *in vitro* fertilization and the history of bioethics in Britain', 'to the central role that putative bioethicists played in *generating* and *harnessing* the demand for bioethics in Britain, as much as they reacted to it.' (Wilson, 2011, p. 124). Ian Kennedy, who as we saw in the last chapter, went on to play a role in the generation of the retained organs scandal nearly two decades later, led the call in the early 1980s for an outside chair to be appointed to a committee to investigate IVF and embryo research. This duly happened with the appointment of Mary Warnock to the position. As Wilson argues:

'Once selected as chair of the government inquiry, she became a strong advocate of what became known as 'bioethics': criticising biomedical paternalism and extolling the benefits of external oversight. Like Ian Kennedy, her rhetoric was not simply a reaction to the growing calls for oversight in this period, but was fundamentally constitutive of it.' (Wilson, 2011, p. 136).

Wilson observes that the appointment of Warnock was consistent with if not of a piece with the 1980s Conservative Government's attack on professional

autonomy, a trend that was to continue, and intensify, under New Labour in the 1990s and beyond: 'successive New Labour Governments have increased the trend toward public scrutiny and accountability in many areas.' (Wilson, 2011, p. 137). But at the same time, bioethics and the new governance structures provided a form of legitimation for research, and in this sense bioethics acted as an intermediary between science and society. This, argues Wilson, is bioethics' key role today, and the source of its enduring influence:

'this reaffirms Rosenberg's claim that, contrary to its "origin myths", bioethics is not, and has never been, a "free-floating, oppositional and socially critical reform movement" (1999, p. 38). In Britain, as elsewhere, it was ultimately about bridging divides, not exacerbating them: deriving workable solutions without fundamentally questioning the forms of power or control invested in modern biomedicine.

Some predict this lack of critical edge will spell bioethics' downfall, but I would argue precisely the opposite (Cooter, 2004). If we see bioethics as a "mediating element" between politics, the public and science, then contemporary society provides it with fertile ground (Rosenberg, 1999, p. 38). The biomedical sector is increasingly seen as a prized component of the so-called "knowledge economy", with politicians and private investors placing great stock in the progress of research (Rose, 2007).' (Wilson, 2011, p. 137).

This observation is an important one. In this chapter I examine in detail some of the issues that Wilson addresses in respect of governance and bioethics. But instead of examining IVF I focus on research pretty much exclusively (though they are of course related), and instead of simply focusing on the role of bioethics I extend the analysis to consider the role of STS / SSK and Democratic Model ideas in governance. As such this chapter addresses both of my research questions. A third difference is that instead of locating governance within a market process first and foremost, I consider some other aspects alongside this, specifically the non-economic political motivations and considerations behind New Labour's embrace of new modes of governance, and look at the consequences of this for research practice in the more recent period. In the next, concluding, chapter I make some critical observations about Wilson's analysis when reflecting on the overall thesis of the changing governance of science.

Alder Hey is the dominant incident in the contemporary refashioning of human tissue governance. It provided a jolt and the background against which the Government crafted and justified a wider change in the governance of human tissue research. The contemporary, that is the most recent, refashioning of human embryo research governance is less dramatic, which is not to say that embryo research is uncontroversial or of less interest to the public and the media. Far from it in fact – the issue is rarely out of the news. But at the level of form and

presentation at least, the Governmental discourse during the most recent Parliamentary discussion leading up to the passage of the Human Fertilisation and Embryology Act 2008 was primarily about the need to update legislation, to ensure that new developments fell within the framework developed in the 1980s and enshrined in the HFE Act 1990, which, it was often claimed, was of proven worth, the envy of the world in fact, and widely accepted within the UK, even if it had its well-known Pro-Life critics.

In outlining the refashioning of embryo research governance I use my data to observe and analyse continuity and change, and within both continuity and change I examine the role of Democratic Model ideas, for it is not just in relation to change that new approaches to governance have had an influence and come to play an important role. I argue that a contribution to continuity with the 1980s is that by adding to the external oversight role of bioethics, Democratic Model ideas both limit professional autonomy while also, within limits, legitimising embryo research. A contribution to discontinuity with the 1980s is that Democratic Model ideas fit in with and bring their own distinct twist to novel aspects of more contemporary patterns of, new modes of, governance, with specific consequences for research practice. Overall, Democratic Model ideas have reinforced a move away from an embryo-centric form of governance to a more pluralistic and also occasionally chaotic one.

I begin, in 6.1 and 6.2, with an analysis of the nature of law and governance of embryo research from the 1980s to the present. In 6.3 I develop this analysis and look at some of the consequences for researchers through a discussion of engagement, pluralism, deliberation, embryos and research. Section 6.4 fleshes out the earlier sections and highlights the distinctive character of what I term Government through new modes of governance, via a brief re-telling of the hybrid embryo research debate in the UK. Taken together sections 6.1 to 6.4 contain an implicit and sometimes-explicit discussion of the changing governance of embryo research, weaved into a narrative style of presentation that aims to capture, as with the tissue story in chapter five, the development of governance as the outcome of conflicts over governance. In 6.5 I explicitly reflect on continuity and change in governance, and others' analysis of similar issues.

### **6.1 Embryo research: a permissive trend and its limits**

Wilson quotes Warnock as arguing that the public were “‘entitled to know, and even to control” professional practices’ (Wilson, 2011, p. 124), and indeed the Warnock Report stated that this applied in particular to research, because unlike with fertility treatment where ‘there was a fairly strong view that the freedom of the individual to take what steps he could had to be respected’ in the case of research, on the other hand, ‘there was general agreement that the issue of individual liberty did not arise.’ (Warnock, 1985, p. xiv).



This underlying assumption is clearly present in the legal and regulatory framework advanced by Warnock. In the UK research on human embryos *in vitro* is permitted subject to certain restrictions and controls. These include: some specific prohibitions; broad categories under which a particular project must fall; and the need for the researcher to obtain a license from a regulator established by statute, the Human Fertilisation and Embryology Authority (HFEA). This pattern of regulation was first established by the passage of the HFE Act 1990. The categories of permitted research were extended in 2001 through a modification to the 1990 Act, and then extended further as a part of a more general overhaul of the legislative framework in the shape of the HFE Act 2008, an Act that also removed some of the specific prohibitions contained in the 1990 legislation, most notably, perhaps, the prohibition on the genetic modification of a research embryo.

In a little more detail, in the most recent Act it seems clear that the Government tried to ensure that most foreseeable research projects using embryos could be licensed. The relevant section of the 2008 Act is this:

*Licences for research...*

(2) The principal purposes are—

- (a) increasing knowledge about serious disease or other serious medical conditions,
- (b) developing treatments for serious disease or other serious medical conditions,
- (c) increasing knowledge about the causes of any congenital disease or congenital medical condition that does not fall within paragraph (a),
- (d) promoting advances in the treatment of infertility,
- (e) increasing knowledge about the causes of miscarriage,
- (f) developing more effective techniques of contraception,
- (g) developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation, or
- (h) increasing knowledge about the development of embryos.

But while the categories (i.e. purposes) are broad and fairly comprehensive, the list of purposes is preceded in the most recent Act by a range of conditions and qualifications that remains essentially unchanged from the 1990 legislation:

Purposes for which activities may be licensed under paragraph 3

3A (1) A licence under paragraph 3 cannot authorise any activity unless the activity appears to the Authority—

- (a) to be necessary or desirable for any of the purposes specified in subparagraph (2) (“the principal purposes”),

- (b) to be necessary or desirable for the purpose of providing knowledge that, in the view of the Authority, may be capable of being applied for the purposes specified in sub-paragraph (2)(a) or (b), or
- (c) to be necessary or desirable for such other purposes as may be specified in regulations.

That broad categories of embryo research are permitted in the UK, and that the trend has been for these categories to expand over time, is taken by a number of analysts as a marker of the research-friendly character of the UK regulatory system (see, e.g., Walters, 2004, and Salter, 2007). More holistically, in other words taking the two aspects together, the purposes and the conditions and qualifications, Ruth Deech, a member of the House of Lords and a former Chair of the HFEA, also thinks that the UK system of regulation is essentially a research-friendly one. More than this, while acknowledging that the UK system can be bureaucratic, she believes that it has allowed the progressive development from the 1990 Act to the 2008 Act to occur and has put the UK at the forefront of research internationally:

'Extensive legal regulation has drawbacks: expense, bureaucracy and a struggle for domination between politicians, churchmen, scientists, clinicians and the public. Yet I feel that its existence in Britain put this small country at the forefront of research and gave it an authoritative voice

in international discussions on embryology. Regulation has enabled progress to be made in tandem with public acceptance and in a safe zone for clinicians and scientists who follow the rules.’ (Deech, 2008, p. 281).

Many opponents of embryo research do not disagree with Deech’s description of the historical development of regulation and research as such. They rather accept aspects of her description but draw different conclusions about its inherent character and morality. As we saw in chapter three, back in the 1980s, some scientists challenged the framework of governance and regulation proposed by Warnock, the framework that in large part became the HFE Act 1990, on the grounds that it was too restrictive and based on hysteria and unscientific approaches to the human embryo. David Albert Jones, a critic of embryo research from a Pro-Life perspective, argues that scientists have come around to endorsing Warnock because it has given them everything they need: ‘the explicit “no status” view is now redundant. Warnock’s approach is more powerful as it uses status language to strip the embryo of status while offering a mechanism to manage public concerns.’ (Jones, 2011). That the Courts have tended to find in favour of clinicians and researchers when cases have been brought, and against Pro-Life campaigners, using purposive interpretations of the legislation in some cases, has only added to the latter’s frustration, and their assessment of the Warnock approach.

The policy, political and legislative debates stretching from 2004, when the UK Government announced it was to update the HFE Act 1990, through to the passage of the new Act in 2008, certainly confirm that the broad balance of forces established by 1990 Act and the conflict that preceded it remain unchanged. This is unsurprising. The UK has a long history of internationally respected research in genetics, embryology and assisted conception.

Controversies have erupted over specific issues, but during the 1980s a pattern was established of scientists and patient groups pitted against largely religious and to an extent conservative (with a small and large c) groups, with less influential criticism coming from other quarters, such as feminism (see, e.g., Spallone, 1989, and Fox, 2009). The former projected, and project, a responsible image and offered and offer the hope of medical benefits, and by and large they won the argument and continue to do so.

In the course of my doctoral research I interviewed politicians, campaigners, scientists, academics, civil servants, policy makers and others. On this basic point, about the balance of forces, there is much agreement, from all sides in the debate. And indeed, based on this, there was a consensus among the interviewees that the outcome of the most recent Parliamentary process was in broad terms predictable. For example, from opposite sides of the debate, Josephine Quintavalle and John Burn not only agree that the outcome of the Parliamentary consideration of embryo research (specifically admixed human

embryo research) was predictable; they also agree on a key reason, the medical benefit argument, using strikingly similar phrases and categories to describe the process by which opinion was shaped, though differences in moral assessment are of course apparent:

'You've only got to line up 200 people in wheelchairs who've been told they're going to be cured and it's a losing battle... At the event organised by Evan Harris outside Parliament [in April 2008] the BBC interviewed people in wheelchairs in favour of hybrid embryo research but not people in wheelchairs opposed. I was deeply upset to see them interviewing a young child to make the case. We need to be extremely cautious about promising a child that he's going to be cured of anything, when the reality is that there won't be cures in his lifetime.' (Interview, Quintavalle, July 2008).

'What I found dramatic about the 2001 stem cell debate, which mirrored this one exactly, was that the Lords voted 2:1 in favour. I thought they might be more vulnerable to persuasion. When it came down to health benefits the Lords voted 2:1 in favour. So I was never in any great doubt that it would win through on this occasion. In some ways, because I thought it would go through, I feel a greater sense of responsibility, because I think you've basically got a predictability about these debates.

People who want health related things to go through can pretty well guarantee to get them through if you get somebody in a wheelchair to go on the television and their mum and dad say “we really hope they can make a treatment”. The general power of those arguments is 2:1 against the religious lobby. But that doesn’t mean the religious lobby is always wrong. So I think we have to use that power with care, because we are to some extent in a one party state when it comes to health benefits.’

(Interview, Burn, July 2008).

But what is less clear is what we should make of the claims made by Salter, Walters, Deech and Jones among others about the nature and consequences of the UK system of governance and regulation. Regarding the nature of governance and regulation, embryo researcher Martin Johnson, who trained under IVF pioneer Robert Edwards, who was a member of the Progress campaign in the 1980s that helped to steer the original Bill through Parliament and who more recently served as scientific advisor to the joint Parliamentary Committee (Commons and Lords) set up to scrutinise the draft Bill published by Government (hereafter called the Scrutiny Committee), expressed the hope, as the latest debate was getting going, that scientists might be ‘Escaping the tyranny of the embryo?’ (Johnson, 2006). A strong sense of the ‘inevitability of the *in vitro* embryo becoming a child permeated discussions in the 1980s’ he argued. ‘There was confusion between the embryo *per se* and the embryo as child-to-be, and

these two interconnected strands of thinking were often not separated effectively.' He detected a shift since the 1980s, implicit rather than explicit, in regulatory and legal judgements, towards making the distinction clearer, one he wanted to push to a logical conclusion by distinguishing between two kinds of embryos: the embryo destined to become a child (or to be given a chance of such an outcome), in other words the IVF embryo; and the research embryo, destined for destruction (Johnson, 2006, p. 2757).

The HFE Act 2008 makes such a distinction, but how significant is this change as a marker of change in the whole pattern of embryo research governance?

Johnson thinks it is significant, but that it is also hard to discern this on account of ambiguity and confusion about the nature of the framework itself, as well as political calculation. Discussing the issue while the recent Bill was going through its final stages, he put it like this:

'I think there is some ambiguity in the Bill because I think the Government was frightened of straying too far from Warnock. The fact that the Scrutiny Committee and in fact the Department [of Health] really and people in Parliament have said effectively that Warnock still provided the moral basis for how we treat the embryo is questionable. Mary Warnock herself when we interviewed her more or less agreed with that, she said it wasn't really about the moral status of the embryo, that was the one thing they



could never agree on, what they could agree on more was on how you treat the embryo. It was a very practical utilitarian approach. So to that extent I think the current Bill does embody the Warnock principle, but not at the level of ethics in the strict sense of the word... I think that the current Bill, in bringing in the concept of the permitted embryo goes a long way along the route I'm talking about.' (Interview, Johnson, July 2008).

Regarding the consequences of governance and changes in governance, as far as some research scientists are concerned the conditions and qualifications contained within the Act are far from trivial, and in practice they have helped to create a complex system of governance that has hindered innovative research. As it was becoming clear what would and would not change with a new Act of Parliament, and reflecting on the recent history of decisions by the regulator, Robin Lovell-Badge, a if not the leading spokesman for the research community during the passage of the Bill, argued that:

'It is often said that the UK laws are permissive, but this is not strictly true. It is a regulatory system in which nothing is allowed without a licence from the HFEA, and the penalties of proceeding without a licence or breaking its conditions are severe...

... this and future governments need to retain the close links with scientists and to act fast when the need arises: there will continue to be

advances, some from the United Kingdom, but many from other countries without the same regulatory constraints. In fact, most of the delays to research in the United Kingdom have not been due to a slowness on the part of scientists to appreciate what is on the horizon or to warn the regulators, but from political accommodation.’ (Lovell-Badge, 2008, pp. 998-1003).

Contrary to David Albert Jones’ view, and that of others of who are critical of embryo research, for some research scientists the fact that in the first decade of the twentieth century a number of issues were taken to Court, some as far as the House of Lords, is a sign not just that regulation under the old Act was struggling to keep pace with developments, but also a problematic consequence of the rule that everything is forbidden unless explicitly permitted. Specifically on international comparisons and Ruth Deech’s argument about the role of the HFEA: as we saw in chapter three, during the Scrutiny Committee discussions Lord Winston, PGD pioneer Professor Winston with his researcher and clinical hat on, disagreed with her on this point. His voice appeared to be a singular and somewhat contrarian one. However, as we also saw in chapter three, his observation that ‘America has an unregulated scientific community and yet it is producing by far the most effective and most published and most respected papers in stem cell biology in the world, even though of course it has a President [George Bush Jnr, at the time] who is set against it’ (Joint Committee on the

Human Tissue and Embryos (Draft) Bill, 2007, p. 66) is supported by researcher Austin Smith, who is also forthright, derisive even, about Deech's claims on this issue:

'They [Government and the HFEA] still seem to be obsessed by the idea that somehow we're ahead of the US because of the Federal ban on funding. Any idiot could just look at the amount of funding from other sources going into this area in the US, the number of researchers, any metric you want to use – it's clear. (Interview, Smith, July 2008).

It is quite possible then that the research framework is becoming or has become less 'embryo-centric' without that implying that researchers have got everything they want.

An assessment of continuity and change in the governance framework for embryo research, and its consequences, will depend on what is considered to be the essence of the original and the contemporary framework, and what makes an assessment of the changes difficult is that, as Johnson hints at, it is far from easy to pin down the essence of the framework itself. The framework has a philosophical aspect to it, but it is also quite subjective and highly political both in its foundation and in its use. It is common to find the framework criticised but also held up as an ideal. Accordingly, statements made about it require interpretation.

Undoubtedly, as Johnson believes, it contains a strong utilitarian dimension, but if researchers are 'escaping the tyranny of the embryo', what, more precisely, are they escaping from, and to where or what?

As discussed in chapter four, in his *Rights, Regulation, and the Technological Revolution* (2008), Roger Brownsword argues that we should understand the category of regulator narrowly but regulation and governance broadly. This is a fruitful way to begin to examine the changing governance of embryo research. Governance is a set of principles, ideas and objectives that provide the basis for steering activity, or its 'top-down' aspects do in particular (captured by the Warnock framework in the 1980s); it is typically the outcome of or is influenced by a battle for influence and control; and it incorporates modes or methods of governance.

## 6.2 From Warnock to ?

In practice of course the three aspects (and others) interact. But consider, rather schematically, the first aspect – a set of principles for steering activity. Mary Warnock, architect of the framework that was substantially integrated into the 1990 Act, argued that *in vitro* embryos should be accorded some respect and protection in law, but not the absolute protection we grant human life after birth. In proposing to allow research, Warnock rejected the Pro-Life position. Less well

known is that she also rejected the argument from potential. This is a complicated subject, not least because there are several arguments from potential and also because the arguments presented by Warnock are in her own introduction to the report rather than the report itself, leaving the question of what Committee members thought somewhat open – as Michael Lockwood pointed out shortly after the report was published, in the body of the report we are given ‘arguments for and against various positions, and we are given conclusions. But the relationship between the two often remains obscure.’ (Lockwood, 1988, p. 187). Nevertheless, it seems fairly clear that Warnock herself argued that the embryo had to be judged on what it is rather than what it would or could become, and what is more she argued that this was the view of the majority on the Committee:

‘The majority of the Committee was not moved by the argument that these cells could, if certain conditions were satisfied, become human beings. They did not rely, that is to say, as the minority did, on ‘potentiality’, but on the consideration of what the embryo was at a particular time, its actual mode of existence immediately after fertilisation.’ (Warnock, 1985, p. xv).

This might seem clear and definitive enough. Warnock however advanced a second line of argument, or a second order argument: within society, sentiment attaches to such embryos and at a fundamental level sentiment is the basis of

morality (Warnock, 1985 and 1987).<sup>2</sup> This view has been criticised by a number of philosophers, notably John Harris. How is this, he asks, a moral argument? And how is sentiment to be judged – should we respect prejudice on this basis? (Harris, 1998). However, the key to Warnock's success was and remains that in the realm of practical politics it worked well; it facilitated and legitimated the process leading up to a vote insofar as the vote in Parliament was an expression of the sentiment of MPs and the conflicting desire to harmonise scientific advance with morality, specifically, back then, support for the traditional family.

Clearly, there are a number of issues in play. Reflecting on the 1980s debate, Michael Mulkay was of the view that the Warnock Report argued for external regulation of embryo research by reference to 'the need to protect the human embryos used for experimental purposes, the need to safeguard the public interest and the need to allay widespread anxiety.' (Mulkay, 1997, p. 20). Writing in 1999, Margot Brazier, an opponent of embryo research, gave emphasis to allaying public concerns and appeasing opponents of the work. But, she suggested, in reality the embryo used in research was accorded no status: 'Are embryos in reality now treated any differently from laboratory artefacts, and treated with caution only because of their tendency to generate moral panic?' (Brazier, 1999, p. 187). More recently, Ruth Deech outlined, in the context of

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<sup>2</sup> Lockwood argued that Warnock's rejection of the argument from potential was at odds with the views of the Committee expressed in the report. I disagree with this. She may have argued differently from some of the Committee, though for the reason given concerning the nature of the report this is hard to judge. But there is no contradiction as such. The key point is to distinguish between arguments based on potentiality and arguments based on the sentiments that people may hold about, among other things, the potential of the embryo.

discussing embryo stem cell research using fully human material, several reasons that may underlie the decision to regulate and restrict embryo research: a loss of potential for development; the symbolic harm to society resulting from embryo destruction – ‘if this is the way we are willing to treat the most vulnerable and helpless members of the human species, what does it say about us as moral beings?’; to appease those who feel the research is wrong; and out of respect for the effort taken to secure the material on which research is conducted. (Deech and Smajdor, 2007, pp. 195-6).

Taken as a whole these analyses and the emphasis given to different aspects seem to point not simply to an evolution of the governance framework, but also to a shift in focus – away from the status of the embryo as such to other rationales for regulation and restriction of research. The move away from an embryo-centric perspective makes further sense when we consider that the broad political and policy context in which all groups operate today is different in some key regards from the 1980s. Back then, Pro-Life views were influential in society, and were very well represented within Parliament. This constituency has less influence today, in part due to the decline in traditional conservative views. So, whereas in the mid 1980s a majority of Parliamentary and public opinion was opposed to embryo research (Mulkay, 1997), this is no longer the case today: in The Commons vote in 2000 on extending the purposes for which research is allowed and in The Commons vote in 2008 on the general question of creating admixed

embryos for research, MPs divided 2:1 in favour (the figures are, respectively, 366:174 and 336:176). Public opinion today divides in roughly the same way (YouGov Daily Telegraph, 2005), and indeed public attitudes towards the creation of cloned embryos and admixed human embryos follow the same pattern, if the question is asked in the context of developing therapies for serious diseases (Shepherd et al, 2007; HFEA, 2007), as it usually is, implicitly or explicitly.

Certainly, it is the self-perception of Pro-Life campaigners that they have lost influence and that governance has changed accordingly. Josephine Quintavalle believes that:

'In 1990 certain protections for the embryo were taken seriously, and there was a big battle, and the clause about embryo research having to be necessary is still a part of the law. With animal-human hybrids our view is that they are not necessary. There's a great difference between 1990 and now, and our battle should have been stronger in 1990. Certainly, the conscience of the nation has dulled. There hasn't been any further focus really on the rights of the embryo or the value of the human embryo, which I find extraordinary in the light of how much we know about the human embryo. The likes of John Burn at Newcastle is happy to repeat endlessly that the human embryo is just like a lump of semolina. I think he's just reinforcing the sense that I think many people in the country have about



what the embryo is about, which is I think extraordinary.’ (Interview, Quintavalle, July 2008).

Calum McKellar, Director of Research, Scottish Council on Human Bioethics, broadly agreed with this assessment, and indeed explicitly contrasted aspects of the 1980s to the present:

‘In the 1990 Act you still had the influence of the Warnock Report, which really was quite strongly in favour of this special moral status of the embryo. Whereas in the current Bill I don’t think the special moral status is mentioned much at all. Basically everybody is considered as a pile of cells... In the 1990 debate, some people believed that they were piles of cells, but the debate was still around the special moral status... It is more research friendly now. There are different MPs, and people’s views have changed.’ (Interview, McKellar, June 2008).

As McKellar suggests, at no point in the recent debates was there a substantive or explicit argument or discussion of the merits of embryo research using fully human material. This amounted to a process of normalisation which was further strengthened by the fact that often the issues considered in the debates on hybrids were more to do with human dignity and slippery slopes on the one side, and medical benefits on the other, than they were to do with the destruction of

what some still regarded as potentially viable life (though this is in fact very doubtful). These themes are present in the academic literature as well as in popular discussion. Concern about human dignity is central to Francis Fukuyama's *Our Posthuman Future* (Fukuyama, 2002). Fukuyama takes Huxley's *Brave New World* very seriously; it is not, as it is for many people, a dystopian novel not to be taken too literally, but rather a prescient analysis of one distinctly possible future. Such is the threat posed by the biotechnology revolution, argues Fukuyama, that it might change human nature and re-start history (recall his famous book, *The End of History and the Last Man*). Fukuyama does not however oppose embryo research entirely and indeed in *Beyond Bioethics: A Proposal for Modernizing the Regulation of Human Biotechnologies* (Fukuyama and Furger, 2006) it is hybrid embryo research in particular that he thinks should be totally blocked rather than human embryo research as such.

The danger of instrumentalising embryonic life is the dominant theme in Jurgen Habermas' *The Future of Human Nature* (Habermas, 2003). Habermas' concern is that once we start instrumentalising the embryo there is no stopping (Habermas, 2003, p. 71). Today's choices have to be assessed in the light of future possibilities, and these include, he fears, a fully eugenic future, in which parents genetically design their children. This is particularly problematic, he believes, not so much because a particular genetic constitution is better than any other, but because for a person to engage with others they must feel that they are

inexchangeable, and this in turn requires that their body is experienced as something natural and non-designed.

In their different ways both Fukuyama and Habermas express strong concerns about embryo research without invoking ideas based on the sanctity of embryonic human life. In the UK context at least, proponents of these and related ideas struggle to make a case against concrete research proposals that carry the political punch Pro-Life arguments made in the 1980s and still do to some extent today. As discussed in chapter two, Fox (2009) complains that objections other than those based on Pro-Life views are squeezed out by a continued focus on a binary research interests versus sanctity of life framing of the debate. As also discussed in chapter two, an alternative analysis is that Pro-Life views lack the purchase and power they had, while non Pro-Life critical theorists and activists find it hard to develop politically persuasive objections to concrete proposals, which formally if less substantively leaves old framings in place.

So, if it is plausible if hard to be precise about the idea that researchers are 'escaping the tyranny of the embryo' does this mean that Pro-Life and other critics are right to argue that governance today simply amounts to letting scientists do pretty much what they want within one of the most research friendly environments in the world? It does not. This brings us to the second and third aspects of governance raised above: it is typically the outcome of or is influenced

by a battle for influence; and it incorporates modes or methods of governance. In the next two sections I look these two aspects of the contemporary governance of embryo research.

### **6.3 Engagement, pluralism, deliberation, embryos and research**

As far as many critics of embryo research are concerned, scientists, Government and regulators, in broad alliance, are firmly on top. But this 'alliance' bears critical examination. The critics' perspective is a one-eyed one, too much influence by the critics' own aims and frustrations. The reality is more complex, and the outcome less research friendly that is often appreciated.

When Government, in publications, and Government Ministers, in debate, did address the specific issue of the status of the embryo in the period 2006 to 2008 they tended to stress the idea of setting boundaries to respect a plurality of views, a respect that it was perceived would be undermined if too much weight was given to vocal, but minority, perspectives. They did this, they argued, in order both to support research and reflect public concerns (see, for example, Department of Health, 2006, p. v and Alan Johnson's speech introducing the Second Reading of the Bill in the Commons, 12 May 2008):

In this spirit, Government consulted and tested the water with a White Paper published in December 2006. It established a joint House of Lords and House of Commons Committee to scrutinise the Bill. And of course the issues were debated in Parliament. On each of these occasions Government made it clear that, while some issues were up for discussion, others were not. This did not as a matter of principle prevent interested parties from raising any issue they wished, but it certainly had the effect of channelling debate and of setting some parameters that could only be changed through a great deal of effort.

In a more focused way the HFEA took a similar approach when it organised a consultation on hybrid embryos in 2007, a consultation that involved public survey work, a public consultation document (HFEA, 2007) as well as detailed, deliberative, discussions with selected audiences. Questions were asked about people's views on research using fully human material, but it was made clear that this work was already legal and would remain so. Primarily, the answers were used to categorise those opposed to and those in favour of hybrid embryo research (see HFEA, 2007a, paragraphs 5.1. to 5.4 in particular). Specifically, the HFEA contextualised the predominance of opponents of hybrid embryo research in the written responses to the consultation document by pointing out that most were also opposed to research using fully human material. Furthermore, by the time the HFEA organised the consultation it was becoming clear that Government was open to the idea of research using hybrid embryos and that the HFEA itself

was keen to support the work. Quite reasonably, this has led to criticism of the idea that the process was in any sense neutral, and also reasonably, at a more general level, it is suggested by others that this kind of scenario is quite typical, such that neutrality within such processes is often or always an illusion, or is at best significantly circumscribed (see, e.g., Baylis, 2009).

What role did the process play, beyond allowing the regulator and Government to move from the proposal to ban hybrid embryo research to licensing it under the 1990 Act and explicitly allowing it under the 2008 Act? In her analysis of the HFEA public consultation on hybrids and chimeras (now all classed together as admixed human embryos in the language used in the HFE Act 2008), commissioned by the HFEA itself, Diane Warburton, while acknowledging the importance of the medical benefit argument, placed a great deal of emphasis on the power of deliberation in the narrow or strict sense of the term over and above anything else. As she stressed during an interview I conducted with her:

‘When people first think about hybrids many can’t help thinking about people’s heads on animal’s bodies. It was the medical benefits idea that shifted it. But I think it wasn’t just that, I think it was familiarity, in the deliberative process... It is the three things: the medical benefit; seeing that the scientists are reasonable people; and just having the time to think about things. With deliberation, because it engages you rationally, logic

and all those sorts of thing come in, and you're talking to other people.'

(Interview, Warburton, July 2008).

However, what is striking about the data is that there was as big a shift in opinion, in fact a *slightly bigger* one, in the opinion poll results as there was in the results from the more intense deliberative process. In the opinion polling this shift was achieved by simply changing the question to stress medical benefit: no discussion or background material was involved. When people were asked: 'To what extent do you agree or disagree with scientists creating an embryo which contains mostly human with a small amount of animal genetic material purely for research?' 34% agreed or strongly agreed, while 48% disagreed or strongly disagreed. However, when people were asked to comment on the following statement: 'I agree with creating embryos which contain mostly human and a small amount of animal genetic material in research if it may help to understand some diseases for example Parkinson's or Motor Neurone Disease.' 61% agreed or strongly agreed and 25% disagreed or strongly disagreed. (This material is taken from a HFEA Authority Paper titled 'Hybrids and Chimeras: Findings of the Consultation', Appendix F, Figure 6, authored by Helen Coath and presented to the Authority at its 5 September 2007 meeting). The 61% figure is, unsurprisingly, the one more commonly referred to by the HFEA. (In passing it is worth noting that the gulf between the two questions is artificially wide: neither represents an accurate picture of the nature of research, one being too far to one side (blue

skies research); the second too far to the other side (an instrumental conception of the nature of research)).

These figures and the centrality of the medical benefit argument reinforce the point made by Quintavalle and Burn, that the debates have a predictability to them, that, roughly speaking, in Parliament and in society during the New Labour years there was a 2:1 majority in favour of embryo research. This in turn could, quite reasonably, be taken as evidence of continuity in governance, of the limited importance of engagement and deliberation as compared with more direct and well-established narratives.

Furthermore, the importance of the medical benefit narrative also puts into context the lobbying efforts of all concerned. For example, the Science Media Centre are wrong to grant themselves and their allies such a central role in turning around public opinion on admixed human embryos in comparison with the failure of scientists to get their message across around GM crops and the MMR vaccine (Watts, 2009). In reality, the overall balance of forces, specifically the power of the medical benefit argument as marshalled by scientists and patient support groups, meant that they were pushing at a door that could fairly easily be opened.



Finally, if the medical benefit argument is important in explaining the success of the campaign in favour of allowing admixed embryo research to take place, it is also important in understanding the hype around the work and the subsequent disappointment and confusion among some of the supporters of the work when it was refused funding. As I discuss in more detail in the next section, many scientists involved in the campaign were aware of the distinction between the in principle importance of allowing the work to continue, and the belief on the other hand that the specific research tool itself was vital to stem cell work as a whole (Interviews, Smith, July 2008 and Minger, March 2009). More than this, some researchers worried about hype (Ian Wilmut has for example warned about this and suggested that it will be decades rather than years before therapies for all but a few conditions are developed using stem cells (Wilmut, 2011)). But in what would appear to be a classic example of MacKenzie's 'certainty trough' in action, some others involved in the campaign were surprised and bitterly disappointed when the work was refused funding in the UK in 2008 and 2009, because, it would appear, they really had come to the view that this particular research tool was vital to the field as a whole and they had missed the other issues in play:

'Two of the three licence holders for admixed embryo research have not been able to get funding, with the third licence holder not having applied yet. Many are surprised by this considering the support this research has had during the passing of the Bill'

[Beth Graham, Institute of Biology Policy Team]

'I find it remarkable given the unprecedented level of support for this research across the scientific community'

[Fiona Fox, Director, Science Media Centre]

'It is difficult to believe that there is no hybrid embryo researcher in Britain good enough to warrant a grant, so this episode prompts an obvious question of the tight-lipped funders: why have these scientists been turned down?'

[Editorial, *The Independent*]

However, having said all this, the centrality of the medical benefit argument both in the past and more recently does not in itself detract from the importance and significance of deliberative processes. On a general level, as one might expect from the theory of Rawls (2005), structuring the renewal of the HFE Act as a deliberative process encouraged all the protagonists to move away from arguments based on core principles and world views to stressing a limited set of arguments. Specifically, in relation to research, in one sense all the protagonists were pushed to debate admixed human embryos because that was the main issue that the process appeared to 'allow' debate on – Quintavalle, for example, may complain about the lack of discussion of the status of the fully human embryo, but then the Pro-Life critics to a large extent accepted that they had lost

that argument and didn't press it. Their complaint was often or more often about being excluded by a process rather than a substantive one about human embryos being used in research.

Irwin makes the important point, and he puts it strongly, that 'far from being a simple input to decision-making processes, public opinion should more accurately be seen as an *output* from particular institutional frameworks and forms of social construction.' (Irwin, 2006, p. 317). This can be extended to cover all opinion, including what counts as scientific opinion in deliberative policy debates. The more critical strands within STS and SSK may regard deliberative processes as tame, usually top down, affairs, more likely to reinforce than to challenge the status quo (Brown, 2009, chapter nine). But we need also to consider all sides of the framings, boundaries and channels they create. As Horst and Irwin suggest, it is true that typically the more radical views are shut out, that is that critical social, ethical and environmental arguments are ruled out and narrower and technical points ruled in. But that is not the whole story, or it might not be:

'For Wynne, talk of consensus characteristically obfuscates more fundamental cultural, political and epistemological questions. We would suggest that as a topic for social analysis we should investigate the performativity of consensus governance in a way that is less about

endpoints than it is about process and less about making explicit policies based on consensus than about identity-formation in a broader political context. When exploring the nature of consensus, the central issue thus shifts from who controls what resources to who participates in the process, and on what terms. In this, adversarial and consensual politics may have more similarities than differences. Meanwhile, the point must be made that consensusing functions both as a democratic ideal and as a mode of problem-solving.' (Horst and Irwin, 2009, p. 121)

The most significant thing about the HFEA consultation on hybrids in 2007 was the framing of the debate in the light of some existing commitments and policy frameworks. With an eye to this, attention has tended to focus on the exclusion of Pro-Life views from the debates in the sense that their contribution was discounted in advance (opponents of hybrid embryo research who also opposed all human embryo research were regarded as 'the usual suspects' (see Moore, 2010; Jones, 2011)). However, those who do not see the need for specific governance arrangements for embryo research and specifically those who saw no need to be concerned about research using hybrid embryos were also excluded.

In practice, the construction of what we might call the representative scientists' view, that hybrid embryo research should be controlled by a competent authority

to reflect the ethical seriousness of the undertaking but allowed in principle on account of its importance to developing cures for human diseases, was not obvious, since most of those who dissented from this package were less visible. Behind the scenes though, as discussed in section 6.4 below, many were alternatively bemused and annoyed at the terms of the debate. And they were annoyed not simply on ethical and philosophical grounds but also because of the practical consequences of the terms of the debate – from a researchers' perspective the process of deliberation and debate can seem like an extended series of hoops and hurdles.

So, in summary, while the medical benefit argument was central, this was developed and played out in the deliberative processes broadly conceived. 'Medical benefit' did not trump or over-ride deliberation, but rather played a role within deliberative processes. Partly as a result of this these processes tended to select scientists who thought the work scientifically important and perhaps medically useful. The substantive success of research scientists in securing permission to pursue a greater range of activities can be located in a decline in the influence of Pro-Life critics of embryo research and a commitment by Government to allow such work. But at the same time, distinct non-Pro-Life ethical and cultural criticism discussed at the end of section 6.2 combined with new forms of governance centred on deliberation discussed in this section have contributed to regulatory complexity in ways that research scientists find

frustrating and difficult to navigate, especially those interested in some controversial and innovative areas. In the next section I flesh this out through a re-telling of the hybrid embryo story, and add in a distinct component to the governance story: New Labour's approach of Government through the new modes of governance.

#### **6.4 New Labour and new modes of governance: a (very brief) re-telling of the hybrid embryos story**

As discussed in chapter three and as outlined at the start of this chapter, the Warnock framework entailed a rejection of medical autonomy in relation to both treatment and especially research. This was not accepted without a struggle with and within the natural science research community, and arguments continue despite the often very positive words spoken and written about the UK system of governance by leading UK scientists. But of course, as with the complaints and assessments of individual human tissue researchers, the important issue is to try to make an overall assessment rather than relying on individual opinion and anecdote. A discussion of the third aspect of governance, modes of governance, in part through a discussion of the issue that dominated discussion of embryo research during debates on the recent Bill, hybrid embryo research, later re-named admixed human embryo research, helps further to develop the analysis of the changing governance of embryo research and its consequences for research.

The Government's initial position was that the research should be banned. Two years later Prime Minister Gordon Brown considered it essential for the future of stem cell research as a whole (Brown, 2008). There are a number of reasons why hybrids became such a dominant issue, some or many of them quite far removed, perhaps, from their intrinsic importance as research tools. But one thing is clear, for the campaigners against and in favour of the work (see, e.g., Watts, 2009) the publically declared assessment is that the final decision to allow the work was a triumph for the researchers and their supporters. That the work was subsequently refused funding and its leading UK scientific proponents have either abandoned the work, left academia, or left the country does not, on its own, suggest that this conventional reading is wrong. What is 'hot' (or simply fashionable) can change rapidly in scientific research. But it is consistent with a different reading of events.

Two reasons to create cybrids featured prominently in debate: first, in order to study how embryonic stem cells can be derived from an adult cell nucleus, with the long-term aim of using embryonic stem cells as the basis for developing stem cell therapies for a wide range of diseases and traumas; and secondly, to study genetic disorders through creating embryonic stem cells from an adult cell nucleus with the relevant mutation. However, while Parliamentary debate was still ongoing, Ian Wilmut, 'father' of Dolly the cloned sheep, abandoned the field of

cloning research in 2007 and switched all his efforts to a new approach, developed by Japanese researcher Shinya Yamanaka, called induced pluripotent stem cells (iPSCs) which does not rely on the use of egg cells at all. This new approach used viruses in the first instance, and later other mechanisms, to directly re-programme the nucleus of a cell (Wilmut et al, 2011).

The ten and more years between the birth of Dolly and this move away from cloning was characterised for Wilmut and others by a struggle to make cloning research using human material work, caused in part by the burdensome and slow moving nature of the UK political and regulatory system. There are other complications as there often are in science: scientific competition is involved and, as Wilmut freely admits, he was also struggling to cope with an industrial tribunal case and new administrative responsibilities. As he said: 'it's a tale of human frailty, and of the complications of research really.' (Interview, Wilmut, July 2008). In the outline that follows, the story of research scientists' attempt to advance cloning-related research is of necessity somewhat abbreviated. But one thing it does not obviously appear to support is a scientific free for all, uninhibited by regulatory and governance structures.

Wilmut's view is that while there are still worthwhile experiments to perform in cloning, it is likely to be judged as a footnote in the history of research into



embryonic stem cells. Austin Smith, who, unlike Wilmut, has never been a great enthusiast for the merits of cell nuclear replacement research, shares this view:

'Yamanaka's work is the way forward, almost certainly. It's clearly where all the major effort will go. Now, it's always possible in science that some roadblock will come up that people haven't envisaged. So you never put all your eggs in one basket. It is also possible that things could be learnt from cybrid embryos. But it's not obvious why you'd necessarily have to use human donor cells; though there could be arguments for it. IPS cell technology doesn't mean scientists shouldn't do nuclear transfer. It just means that we've moved from a position where that was the only foreseeable route and everyone knew it was deeply unsatisfactory to a position where we can now see a much simpler and cleaner route. So it's just obvious where you put most of your money.' (Interview, Smith, July 2008).

John Burn at Newcastle doesn't necessarily disagree with the point about the footnote, but he thinks all research tools might turn out to be footnotes. This is where scientific competition enters the story:

'Induced pluripotency is a good example of eleven year olds playing football. One in goal and ten chase the ball. As soon as iPSC came along

it was “let’s all rush over there” before they’d had a chance to look at the outcome... Edinburgh were not well placed to pursue the human embryonic route, so inevitably Ian Wilmut’s going to say “we’ll try this one” [iPSCs] because it plays to their strengths. The embryonic one plays to our strengths. So we’re going to major on that because it gives us an edge when it comes to competing for research funds. But that’s not to exclude everything else.’ (Interview, Burn, July 2008).

However, what Wilmut and Burn agree about is that the best argument for pursuing hybrid embryo research, cybrids in particular, is or was to compare and contrast hybrids with fully human material, or with material from the same species (later, Stephen Minger was refused funding for a study to investigate and compare iPSCs and cells derived from cybrid embryos (Connor, 2009)). Burn believes Newcastle scientists were set up well to do that. Wilmut on the other hand believes that the time when cybrids embryos were most relevant from this point of view was around 2004 or 2005:

‘To me the significance of the hybrid embryos, if we call them that, is probably about three or four years ago... There was a time when the cells produced in Shanghai by Professor Sheng and her colleagues were the only cells which were approaching being equivalent to embryo stem cells that had been produced with a human nucleus, and they were produced

by putting human nuclei into rabbit oocytes. So it seemed important to follow that up. The second reason for doing it was that if you contrasted what happened during the first 24 hours if you put a human nucleus into a rabbit oocyte and a rabbit into a rabbit you might learn something about the differences between the species which were at that time believed to be unknown but causing the failure of primate nuclear transfer. So at that time it seemed a very appropriate thing to think of doing, and for that reason it may still be appropriate in order to learn about the cloning process but I don't see nuclear transfer in this way as having a big impact any more.' (Interview, Wilmut, July 2008).

It was his attempts to do the comparison at the time that brought Wilmut up against practical barriers, as Burn suggests, but also regulatory and political ones. Wilmut makes the following observation, linking his views on the time period in which the work was most relevant to his views on the political process:

'The political system was slow to deal with this in this country, so that by the time that Parliament was debating it we already knew from work in Boston that the procedure [admixed cnr] was not going to produce embryo stem cell lines very efficiently, if at all. The thing which was critical to do was to try to repeat Sheng's work and to see if it could be improved. The evidence so far is that it's difficult to repeat and there's no evidence of

improvement. But at that point, in the absence of Yamanaka's work, it was an important thing to follow.' (Interview, Wilmut, July 2008).

When he tried to investigate fully human cloned embryos and hybrids in parallel, first one leg of the procedure proved difficult to implement, then the other was blocked. He had invested a lot of energy in developing a collaboration with the South Korean scientist Hwang, who appeared to be doing better work in human cloning research than anyone else. When it was discovered, in 2005, that many of the results had been faked, it was quite a body blow to Wilmut for a whole number of reasons. Not the least of these was that he had already spent four years negotiating the regulatory and scientific hurdles in an attempt to get to the point where he could start to work on cloning using fully human material. But he picked himself up, and began discussions with colleagues locally about securing a supply of fresh human eggs, only for the other leg of the process to be blocked by Government:

'I went across to the clinic one morning, I thought I'd got animal oocytes in the bag at that point, we were likely to get permission... We came up with an algorithm [for the procurement of human oocytes] that said roughly that the first six oocytes would go to the couple, and then progressively as it went on past that we would get more. That conversation was 11 o'clock one day. At one o'clock that day I got a phone call from someone in the

HFEA to inform me that the Government had just announced that it was minded to ban the use of animal oocytes... it was probably November 2006. I thought "oh bugger this" and sort of lost patience and kept on doing other things.' (Interview, Wilmut, July 2008).

One year later his interest ended altogether. Smith picks up the story of what happened when the Government announced that it planned to ban work using hybrid embryos late in 2006:

'The Government White Paper saying they would ban this area was just gob-smacking... If you talk to the public, and ask, is it better to put a woman through hormonal stimulation to get human eggs or should you go down to the abattoir and get cow eggs? It's a no brainer. So why do we get so exercised? It's just a very, very bizarre place to be in I think.'

(Interview, Smith, July 2008).

In response to this, says Smith, scientists had to make a number of pragmatic decisions. One was to work within the framework of UK law, though he demurs at the suggestion that this entailed expressing strong support for the HFEA:

'You're faced with the reality of UK law, that the way to deal with that situation is to get these things recognised as human embryos so they can

be licensed for research. If you don't do that, there's a problem... From the point of view of the scientists you just want to do the bloody experiment. When these kinds of situations arise, and you suddenly find there's some political threat, some regulatory threat, then all you're interested in is finding your way round that... the key thing was to have these entities recognised as human embryos and therefore covered by the Act, and unfortunately that means we have to take the HFEA as well! So it was a marriage of convenience I suppose. I guess that may also be why any criticism of the HFEA was rather muted, because the key point was to have these entities recognised under the Act, and therefore it would be difficult to argue at the same time that we should get rid of the HFEA, although I still think logically that you could have argued that, but apparently not to politicians.' (Interview, Smith, July 2008).

Smith also makes a distinction, to explain who was defending what during the discussions in the first half of 2007:

'For me it [hybrid embryo research] was symbolically important to protect but not practically. Many of the other scientists started off from the position that this was practically important to protect. This was a rapidly changing time in science. The implications of Yamanaka, people just hadn't realised.' (Interview, Smith, July 2008).

Yamanaka's work is mentioned only very briefly in the hearings. Developing the point about defending the principle as opposed to defending the actual research, in Smith's view there was a reason for the low profile given to Yamanaka's work beyond the fact that his work using human cells had not been published at the time:

'The context of the hearings was to defend this area of research [hybrids] so you didn't actually want to say at this point, well, you know, here's a new technology that is the way forward so we don't need this any more because, you know, you'd be shooting yourself in the foot.' (Interview, Smith, July 2008).

It was not just that scientists rebelled against the idea of banning research and wanted to fight for the principle that research that carried no risk of harm should be allowed. Instinctively scientists were also unhappy because they felt that complete ignorance of biology was leading to an attempt to impose rigid notions, rigid categories, on complex biological phenomena. Professor Martin Bobrow put it succinctly, and a little tactfully, during an evidence session to inform the Science and Technology Committee's inquiry on the subject:

'There is a huge gradation of everything from a single gene in an otherwise completely mouse cell to the reciprocal, and somewhere along there we have to draw a line. The definitions of humanity that I know about all apply to things that walk upon the earth rather than things that live on the bottom of the Petrie dish and I am not sure that there is a straightforward answer [to the question of whether hybrids are human or not].' (House of Commons Science and Technology Committee (2007), p. Ev 38).

A counter discourse to the political view that hybrids are a distinct category requiring clear definition and sensitive treatment became somewhat public in this way and in particular through The Academy of Medical Science's publication *Inter-species embryos* (The Academy of Medical Sciences, 2007) produced by a Committee chaired by Bobrow. This was wrapped up with many scientists' desire to carve out a publicly recognised space for their expertise and autonomy. The convergence of the two strands, the mediation of them, was through the Scrutiny Committee's idea that discretion should be given to the regulator to work with scientists in licensing novel applications, and that in principle most conceivable forms of human or admixed human embryo should be able to be created for research purposes. Further public and Parliamentary controversy was to follow, but at the level of political deal making this resolved the issue.



Commenting around the same time on the renewal of the Act, and related matters, Mary Warnock argued:

‘One may generalise from the case of IVF to other cases where it is feared that dedicated and ambitious scientists and doctors may pursue research that some members of society find repugnant. Examples include embryonic stem-cell research, therapeutic cloning and the construction of mixed-species embryos for research purposes. But it is essential that ignorance and prejudice should not be allowed to dictate the outcome. Everyone should be educated so as to have a broad understanding of science and an appreciation of its potential for good. Without this we cannot responsibly erect barriers to scientific advance.’ (Warnock, 2007).

This is, by modern standards an old fashioned way of putting things, though it remains of course a distinct strand in contemporary governance. Bobrow and the Scrutiny Committee, with greater delicacy of language perhaps, had managed to inject some of this thinking into consideration of the Bill by this point in time, and no doubt Wilmut may have wished that a larger dose of that thinking had guided the regulator in the years prior to 2007. That it hadn’t is at least in part because other ideas, associated with new modes of governance, were and are in play. As discussed in chapter one, Lyall et al describe some of these and the problems that they give rise to:

‘Salamon (2002a, 37) describes the result of the “paradox of third-party government” where policy-makers seem to be under increasing political pressures to select those tools of public action that are most difficult to manage and the hardest to keep focused on their primary objectives. Indeed, many of these new tools of governance are horizontal (Ringeling 2002, 588-9) – communication / public information; networking; public-private partnership – and not based on a view of government controlling the actions of others.’ (Lyll, Papaioannou and Smith, 2009, p. 9).

And as discussed in chapters four and five, while New Labour, like and in some ways more than the previous Conservative Government, put a great deal of resources into natural science research, at the same time it was keen to take on board or show it was listening to public concerns, real or imagined. Initiatives that met both objectives were very appealing. To put the point slightly more strongly, New Labour’s approach to securing licences to practise, or its way of encouraging others to do so, ran alongside and included an activist and populist approach to engagement and governance, which gave a particular twist to the interaction of traditional elite approaches to governance as advocated by Warnock and the new modes of governance outlined by Lyall et al. This is perhaps the best explanation of the Chief Medical Officer’s decision in the year

2000 to recommend a ban on hybrid embryo research and the Government's commitment to enact such a prohibition in primary legislation.

Three years after the public announcement of the birth of Dolly the cloned sheep, the Chief Medical Officer's Expert Group and the Government, wildly optimistically as it turned out, thought that maybe 12 or 13 human eggs on average might be needed to produce an embryo stem cell line for therapeutic research by the same method of cell nuclear replacement. This, they believed, was highly desirable and important enough to prompt a change in the law to make it possible. But for no plausible scientific reason they also saw fit to create what turned out to be a striking hostage to fortune:

'The Expert Group concluded that the use of eggs from a non-human species to carry a human cell nucleus was not a realistic or desirable solution to the possible lack of human eggs for research or subsequent treatment.' (Department of Health, 2000, para. 31).

'The Government agrees with the Report's conclusion that the mixing of human adult (somatic) cells with the live eggs of any animal species should not be permitted. Primary legislation to give effect to this recommendation will be brought forward when the Parliamentary timetable allows. In the meantime the Government calls on bodies funding research

to make it clear that they will not fund or support research involving the creation of such hybrids.’ (Department of Health, 2000a, para. 8).

In the end, sections of the scientific community and its allies managed to turn this around, but at the cost of a considerable expenditure of energy on a topic Smith described as a ‘no brainer’, only through reinforcing patterns of bureaucratic regulation some had hoped to change, and too late in the day, in the opinion of Wilmut at least, to perform relevant and timely experiments.

### **6.5 Conclusion: the changing governance of embryo research**

Formally speaking the underlying philosophy of the 2008 Act is the same as the 1990 Act, which was based on the work of the Warnock Commission in the 1980s. But appearances can be and in this case are slightly deceptive. In particular, while there is much continuity between the 1980s and the present, there are also some key differences. Democratic Model approaches and ideas have come to play a role alongside bioethics in reinforcing and creating both continuity and discontinuity.

Sarah Franklin argues that ‘social anthropologists would agree there is no such thing as “an absolute truth about the moral status of the human embryo”.’ ‘Scientifically’, she suggests, ““embryo” is a basket category – like “clone”, it is

famously imprecise. Legally, it is an equally indeterminate appellation, and philosophically it has been the subject of debate for more than two millennia (Dunstan, 1990)' (Franklin, 2010, p. 505). Franklin goes on to argue that:

'Warnock and her committee did not make new laws, they were supposed to advise ministers with a view to later legislation. Indeed the legislation was much later – six years in fact. The exceptional difficulties that needed to be overcome in the process of successfully enacting viable UK legislation in the area of human fertilization and embryology is confirmed by the near complete absence of a similarly detailed legislative response to the dawn of the post-IVF era anywhere else in the world.

The "hope" lesson here, if we are to use that word in the aspirational sense that is currently popular (as opposed to the Hegelian or Marxian sense of it as illusory) would be for more legislative initiatives like that initiated by Warnock that both show respect for diversity, and use discordances as a resource in the effort to create a workable and sustainable compromise. One way to describe the fundamental principle of such a "technology of hope" for the law would indeed be "sociological", or even "anthropological" in its understanding of morality as binding because it is felt as well as understood, because it is collective as well as individual, and because it is accepted in the spirit of toleration not absolutism.'

(Franklin, 2010, p. 508).

The toleration of which Franklin writes included not only a rejection of the Pro-Life perspective, but also, as I argued in the introduction to this chapter, a firm rejection of old notions of professional autonomy in this area. This characteristic of the Warnock framework is as influential today as it was in the 1980s. But beyond the similarities and continuities between the present and the past, however one views the merits and demerits of those continuities (Franklin's is a very sympathetic reading), there are also some differences. The pluralism and toleration that Franklin detects in the Warnock framework, setting aside for the moment that those whose views are marginalised might not see it that way, is in some ways more of a defining feature of its mutated, contemporary form. This mutation was influenced by the decline in the influence of Pro-Life views from the 1980s to the present and the way in which the formal framework was used as a resource in the major debate that did take place, over hybrids embryos, rather than being discussed on its merits, which led to or reinforced a trend towards a diminution in the specificity of governance arrangements in this area.

So, broadly speaking, the direction is away from an embryo centric regulatory system. It is however hard to be definitive about this, for three reasons: there is a degree of opacity to the governance framework; the stated basis of the framework is today the same as it was back in the '80s, the special status of the embryo; and based on the first two points participants in the debate could choose

to accentuate or play down aspects of the framework for instrumental ends (for further discussion and debate on some of these issues see Jacob and Prainsack, 2010).

In terms of a core concern of this thesis: What are the consequences of this evolution for natural science research? The HFE Act 2008 was the culmination of a process of political debate stretching back over the preceding five or six years. Such was the consensus on some basic questions that before and to an extent during the battle over admixed human embryos the scientific community was pushing, tentatively, for a liberalisation of the regulatory regime, a more 'research-friendly' structure, rather than merely defending the status quo. And in one way the 2008 Act is more permissive if not liberal than its predecessor, in the sense that it allows a wider range of research activities than the HFE Act 1990.

The House of Commons Science and Technology Committee, and in particular two members of the Committee, its Chair at the time, Labour MP Ian Gibson, and the Lib Dem MP Evan Harris, spearheaded the attempt to liberalise the regulatory regime. Overall, the attempt failed, in part because there were too many different perspectives and aims in play. At the Parliamentary level Gibson was particularly concerned to ensure some decisions were taken by MPs rather than the regulator. Harris shared this concern to an extent but was perhaps more concerned to make sure the research framework allowed as many new forms of

research as possible, an approach for which he was criticised by Gibson in the end (Interviews with Gibson and Harris, October 2008 and January 2009).

Natural scientists became concerned that if they did open themselves up too much to political decision-making along the lines advocated by Gibson, in keeping in some ways with the new modes of governance approach, it might make things worse. Better the devil you know became an influential viewpoint.

Critics argue that researchers can get away with anything. However, some researchers are in fact far from happy. They had to fight over something they hoped they wouldn't have needed to. When the dust settled, what had they got? Regulatory restrictions based on respecting a plurality of views may be no less onerous than those based on respecting the embryo. Once again it is hard to be definitive about this. A number of factors, some replicable, others perhaps very specific to time and place, created a brouhaha around hybrid embryos. How the regulation of admixed human embryo research will develop in practice remains an open question, and indeed we may never know because the research may never take place, unless of course Burn is right about those crazy kids getting over-excited about iPS cells, and hybrids make a research comeback. More generally it remains to be seen how future governance decisions are made and how future debates play out.



The UK is undoubtedly, compared with many other countries, an attractive place to conduct embryo research. Drawing on Levine's study of the geographical preferences of stem cell scientists (Levine, 2010), Lovell-Badge's summary assessment is that:

'Research remains strong, and a recent analysis of publications suggested that there is a direct link between the type of regulation and achievements in this area of biomedicine, with the United Kingdom "overperforming" in comparison with many other countries, including the United States....'

However, while accepting that knowing where the barriers are is comforting for scientists, Lovell-Badge is wary of taking the international comparisons at face value. He goes on to argue that:

... if true, this has been in spite of substantial legislative delays in the United Kingdom. For example, the first human ES-cell lines were derived in the United Kingdom 5 years after Thomson first achieved this in the United States.' (Lovell-Badge, 2008, p. 998).

If one trend over the past twenty years has been in the direction of normalising embryo research, a corollary of that trend is that some areas of research and innovation have become normally problematic: governance is less 'embryo-

centric' than it was; at the same time it is subject to the general dynamics of the new modes of science governance typical of controversial areas of research and innovation. In terms of the consequences of contemporary governance for research performance, a summary might be that while the UK has had a long lead in this area of research, with some key technologies and clinical achievements being pioneered in the UK – IVF itself and PGD being the obvious examples – these were some time ago now and, regarding Ruth Deech's arguments about the central role of the regulator, before the HFEA existed. The UK continues to punch above its weight, as Deech puts it, echoing former UK Foreign Secretary Douglas Hurd, but perhaps now it is better suited to developing work in the mainstream rather than innovating at the edges of knowledge where speed and freedom from bureaucratic delays is important.

## **Chapter Seven: Conclusions on the Changing Governance of Science**

Investigation for this PhD was guided by these two questions:

To what extent and in what way do governance regimes incorporate proposals and approaches developed by social scientists, Science and Technology Studies and Sociology of Scientific Knowledge theorists in particular, and taken up by a range of actors in response to the perceived failures of older regimes?

What are the impacts of contemporary governance regimes on natural scientific research?

The time period studied was, roughly speaking, the years of the three consecutive New Labour Governments, which ran from 1997 to 2010, though the build up to this period was considered and comparisons were drawn with earlier periods, especially distinct periods after the Second World War, in order to contextualise contemporary governance and changes in governance. I used two case studies to inform the research on the main questions, research using human tissue and research using human embryos. In regard to both case studies, new Acts of Parliament were passed during the New Labour years, following extensive public and Parliamentary debate (The Human Tissue Act

2004 and The Human Embryology Act 2008 respectively). To assist with the analysis of the two main research questions, I used the case studies to, in particular, develop answers to the following:

What role do important themes in the discourse of contemporary governance, specifically precaution, participation, engagement, pluralism and deliberation, play in its substantive constitution?

In my thesis STS and SSK approaches are drawn upon as well as situated within political and governmental processes. In keeping with this reflexive methodology, one that also takes public actors' roles seriously, the detail and various kinds of data are to some degree blended into the thesis as a whole, and comparisons are made across a number of areas. Notwithstanding this, in developing the general argument I endeavoured to use material from the two case studies rather than other areas of natural science research, and I concentrated a good deal of detail about and discussion of the two case studies into two chapters, chapters five and six.

My novel contribution is to link, in detail and with evidence, STS / SSK to governance and natural science research. In this concluding chapter I draw together my discussion of STS / SSK and my answers to the research questions. I make the argument that while there is much continuity between old and new

forms of natural science research governance, there have been changes, which have affected the way some areas of natural science research are carried out in the UK. Some of these changes are the result of the work of various actors, including some STS and SSK theorists, perhaps in ways that they did not know or did not intend.

### **7.1 The case studies: comparisons and generalisations**

In both case studies, through law, regulation and some ethical and social science analysis and critique, natural science research as an activity was pinpointed as deserving of particular attention and control. Mary Warnock made this explicit when her Commission considered embryo research in the 1980s. It is perhaps slightly less obvious in relation to human tissue research, but it is a consequence if not always the explicit intention of the network of governance arrangements for research in this area. As discussed in chapter five, at a general level Dixon-Woods and Ashcroft note that, as far as the human tissue and human data research community is concerned, 'it is the designation of an activity as research that is today critical to how it is controlled, not the inherent "riskiness" of the activity.' It is the social characterisation of the activity and, crucially, the range of institutional arrangements that follow from this that is the cause of the difficulties for researchers:

'The institutional risk (the one that requires the institution to be able to make displays of the robustness of its systems) takes priority over the risks to society. The social policing of ethics and governance itself reinforces this tendency... the practical consequence for researchers is that procedural compliance with regulatory requirements is inescapable.' (Dixon-Woods and Ashcroft, 2008, p. 387).

In chapters five and six I charted changes to the governance of natural scientific research in these areas and the consequences for natural science research. The two issues are closely linked. A range of scholars has closely studied both case studies and different writers have come to different conclusions on some similar issues. As I argued in chapter one, different framings and different starting points influence the conclusions reached. In my own case one key framing was to take the concerns of natural scientific researchers more on their own terms than do some social science researchers. Whereas some social scientists treat natural scientists as the objective 'other', I tried to engage with natural scientists more in the spirit of Max Weber's *verstehen* or 'empathetic understanding'; I tried to understand their concerns in terms of the realities of research practice, for individuals and groups. This was achieved in part by my choice of research questions. In particular the second question (what are the impacts of contemporary governance regimes on natural scientific research?), while secondary in overall importance to the first question within my research, helped

to provide a particular focus to investigation of the first question. Indeed, it provided a measure of change, to some extent. Accordingly, some of my characterisation of changes in governance was achieved through a discussion of the consequences for research practice.

In the remainder of this section and the rest of this concluding chapter I step back a little from the consequences to focus directly on what the case studies, taken together, tell us about the first research question – to what extent and in what way do governance regimes incorporate proposals and approaches developed by social scientists, Science and Technology Studies and Sociology of Scientific Knowledge theorists in particular, and taken up by a range of actors in response to the perceived failures of older regimes?

As we saw in chapter one, Jonathan Porritt, a former Director of Friends of the Earth and an advisor to both Prince Charles and Tony Blair when he was Prime Minister, believed that in the aftermath of the BSE debacle science would only regain public trust if it became 'more precautionary; more participative; less arrogant; less compromised by its paymasters; more compassionate; and more holistic.' (Porritt, 2000, pp. 33; 136). STS / SSK's approach to natural science governance shares many characteristics with the approach advocated by Porritt, and indeed at a practical and policy level there are a number of connections between academic and non-academic players. STS and SSK's approach was

labelled the 'Democratic Model' by social scientists Alan Irwin and Peter Healey in a submission to the important House of Lords inquiry into *Science and Society* (published in 2000). Ian Hargreaves, former editor of the *Independent*, championed this framework, and argued that it should include ideas of 'socially, economically and environmentally sustainable development' and be "based largely on participatory processes in which publics (as citizens and consumers) predominate". (Hargreaves and Ferguson, 2000, p. 11). As I went on to discuss in chapter two, while it is perhaps the case that the most widely known STS and SSK studies cover agricultural and environmental issues, the analysis has been applied to a much wider range of cases. Indeed leading STS and SSK scholar Brian Wynne argues that the trends he is concerned about affect all areas of science:

'We have meandered blindly from nuclear power in the relatively early post-war years of institutional science advice for policy, through a dense variety of other imbroglios involving scientific knowledge as supposed public policy authority, including thalidomide and other pharmaceuticals, chemical pesticides, food irradiation, chlorofluorocarbons, whooping cough and later MMR triple vaccines, radioactive waste management and disposal, waste incineration, oil and gas rig environmental risk assessment and disposal, BSE, high voltage power lines, and other electromagnetic fields.' (Wynne, 2006, p. 213).



Even medical genetics, widely seen as an area of science and medical practice in which professionals and patients work closely together based on a high level of trust, is not immune to the corrosive influence of institutional scientific arrogance according to Wynne (Wynne, 2006, p. 212). The alternative to traditional governance arrangements, argue critical STS and SSK scholars is a hermeneutic project, drawing upon critics of Enlightenment rationality such as Ernst Bloch, Theodor Adorno and Max Horkheimer.

In summary, the most general and important theme of the strand of STS and SSK the core interests of which are political and institutional is a critique of what it regards as the instrumentalism and urge to control that it believes animates modern science and its leading institutions. Implicitly and at times explicitly this critique contains the projection of an alternative that draws on some strands of anti-modernist, environmental and feminist thinking, which in turn, returning to more modest policy-oriented goals, it is hoped can provide resources to change the practice of science.

As we saw in chapter five, STS academic Richard Tutton hoped and to a degree believed that such ideas and goals had influenced the emerging new governance of human tissue research in the aftermath of Alder Hey. The medical profession was criticised for its arrogance, for its instrumental approach to human bodily

material and for its disregard of patients' feelings, interests and concerns. Legislation was brought in with the explicit aim of not just remedying specific wrongs but of driving through a change in the culture of research. As Simon Denegri observes, the steps New Labour took in this area were of a piece with its ambition to challenge the power and autonomy of some of the traditional professions:

'There was a pretty overt agenda at the time about wanting to smash the professions and the hold the professions had over the health service. So there were probably lots of political reasons for why they rammed it quite hard, well, very hard, from the outset. And there were very strong advocates for the patient voice within the Department – such as Harry Cayton and Claire Rayner; these were people New Labour trusted from its very first days in office and had built strong relationships with, who were on the rise as compared with some of the clinical leaders.' (Interview, Denegri, April 2011).

At the same time, Government was subjectively and in many ways practically very much in favour of aspects of, if not much of, medical research and practice. It was, for example, around the same period, re-organising cancer services and research in a way that included a particular enthusiasm for clinical research and an injection of extra money. Of a piece with enthusiasm for research and in tune

with its centralising tendencies, New Labour was keen to promote a system of consent for researchers working with larger, organised, collections of material for research: biobanks. A number of leading researchers and professional bodies were closely involved in developing these initiatives and new structures. Linked to the thinking behind biobanks, in legislation and in the political and policy debates that have taken place over the past fifteen years, human tissue research governance has been closely tied together with Government, Research Councils and other funders' initiatives to encourage the archiving of research data.

Taken together, two trends – the encroachment of ethical and legal codes on the indefinite retention of and the direct peer-to-peer sharing of some kinds of sensitive and rich data by researchers themselves and the centralised storage and linking of potentially sensitive data – point in the direction of archiving of standardised and partially anonymised research data sets overseen by Governmental and quasi-Governmental bodies. This is occurring across both the social and natural sciences today. But while this is a relatively new issue for the social sciences it is a longer standing one in some areas of natural science that deal with large data sets and potentially sensitive material and information, such as human genomics, human tissue and human medical data research. And it is one many researchers are unhappy about, in part because of the lack of trust in them that it involves, in part because of the complexity in some areas and in part because in some cases access to what is truly interesting and important for

researchers, rich, identifiable data, has been made difficult by the replacement of norms based on professional discretion and confidentiality with others drawn from data protection and rights-based thinking. Some ethicists and social scientists had little sympathy when natural scientists complained about transformations to practice over the past 15 to 20 years, seeing natural science as the object to be critiqued and reformed. A more fruitful approach would have been and would be to see commonalities between natural scientists and social scientists as researchers keen to generate, access and share rich data within their respective communities for the production of robust results.

The Government thought it was, or found it easy to believe that it was, possible to promote both human tissue research and an agenda of patient choice and participation that drew upon aspects of the Democratic Model. In practice what this led to was a system of governance in which aspects of the Democratic Model were performed by Government and regulators in such a way that restrictions were placed on researchers, traditional medical and researcher autonomy was challenged, all without much evidence that the broader public really cared one way or another.

In so far as power was transferred, it was from the medical profession to governance agencies. As a real believer in the need for substantive, literal, participation in this area, Jean McHale (2011), points out, anonymisation of tissue

and data and the centralisation of control over information works to deny substantive participation. There is power in this observation even though I would disagree with her belief that the public positively wants to participate and her claim that current practice risks bringing about another crisis of confidence similar to Alder Hey (she believes anonymisation and anonymised research are legally problematic, thinks proposals on the table to deal with some issues can't work, and wants a commission akin to the Warnock Commission of the 1980s into embryology to look into the whole area). This illustrates a point made in chapter three, that in assessing the role of ideas associated with STS / SSK theorists in governance the important point to look at is what the ideas 'do' when they become a part of debate and a part of processes. The ideas have in practice contributed, perversely perhaps for some of those most committed to them, to channelling and closing down debate, and to reinforcing untoward trends in research governance (untoward from some perspectives), such as centralisation, a premature demand for 'relevance' and bureaucratic management of specialist and professional activity.

I turn now to consider the changing governance of embryo research and some generalisations from it. At the beginning of chapter three I outlined how the patterns of research governance established after World War Two had changed, in particular since the 1980s. The post war system relied heavily on scientists' self-governing structures. The deal was that in return for funding and autonomy

scientists would deliver advances in knowledge and useful applications (and munitions and defence systems). There were close ties between scientific, political, economic and military elites, and change was managed through, on the whole, elite policy formation. Some issues attracted a great deal of public interest, but even in these contexts, elites would still aim to manage and control the broad direction of research, while controversies tended to be around specific applications of science. Analysis or attention tended to focus on the use or abuse of science, with the science itself viewed in fairly neutral terms. This was a model of science and governance that, in broad terms, many on the old left (such as J. D. Bernal) endorsed just as did the old right (Gillott and Kumar, 1995, chapter six).

While posing a challenge to researcher autonomy, as I argued at the beginning of chapter six, Mary Warnock's inquiry into human embryo research during the 1980s was still influenced by these approaches to policy formation. A committee of the great and the good took on the role of deciding policy. Where appropriate, soundings were taken of public opinion to inform elite deliberations, but that was about as far as it went. As we also saw in chapter six, Warnock herself took a similar approach in the advice she offered to those reworking the governance of embryo research in 2007:

'One may generalise from the case of IVF to other cases where it is feared that dedicated and ambitious scientists and doctors may pursue research that some members of society find repugnant. Examples include embryonic stem-cell research, therapeutic cloning and the construction of mixed-species embryos for research purposes. But it is essential that ignorance and prejudice should not be allowed to dictate the outcome. Everyone should be educated so as to have a broad understanding of science and an appreciation of its potential for good. Without this we cannot responsibly erect barriers to scientific advance.' (Warnock, 2007).

Many STS and SSK scholars believe that this is really how governance still works. The elite thinks the public needs educating out of its ignorance, and in the meantime the decisions are best kept to an informed few. One initiative to challenge this approach was upstream engagement, which it was hoped would open up debates on science to a wider set of framings:

'upstream engagement may well mean far more than just early public debate at a point prior to polarized opinions or significant research and development. Rather, it will involve an ongoing cycle of dialogue among affected parties. Therefore, the agenda will need to move from industry product based debate (found in downstream dialogue) to broader framing of the issues. This will involve unpacking the assumptions that go into

science alongside exploring how technologies fit in with forms of society that citizens wish to have. Thus ideally debating visions all parties have for society and how the technologies can/should/could and cannot be developed to fit within these. This path of deliberating societal visions and assumptions may even lead to exploring some more radical ways of approaching the interaction of citizens and science that have yet to be conceptualized. In the wake of the GM and BSE affairs in Europe, nanotechnologies may well have arrived at a time where there is genuine opportunity to try something different.' (Pidgeon and Rogers-Hayden, 2007, pp. 360-1).

Human tissue governance was recast during a particularly febrile political moment during the New Labour years. As Pidgeon and Rogers-Hayden noted, endorsing the views of one of their interviewees, there was no guarantee that this would last:

“...there is an opportunity now which there won't be in three or four years time and probably wasn't there three or four years ago to ask quite deep questions about new technology development trajectories... in the UK it will be because memories of the GM debate will fade, the furore will fade and so [will] the willingness of decision makers to take on board new lessons, new ways of working, new ways of thinking about things, lessons



about technologies, society and interaction... It's a political opening not a technological one although it does coincide with a technological one."

(Civil Society member, interview, 2004)' (Pidgeon and Rogers-Hayden, pp. 360-1).

And indeed things did settle down. The reworking of human embryo research governance took place on terms more amenable to research scientists. What is more, they also benefited from established relationships with patient groups and parliamentarians who were powerful advocates for research. These differences with the governance of human tissue research should not be overstated, however.

Aspects of and in some ways the entire reworking of human embryo research governance took the form of a controlled deliberative process. And while it is the managerial character of deliberative processes that the more critical strands in STS and SSK often highlight and criticise (Brown, 2009, chapter nine), these criticisms, reasonable as they are in some ways, can also obscure some less obvious consequences.

The whole furore over hybrid embryos was in large part down to a gesture made in 2000 (a promise to ban their use) and a commitment to taking deliberation seriously. Deliberation is therefore not window-dressing in this context. There is

an amusing, somewhat circular, but also serious point to be made here about the relationship between high theory and on the ground policy. Some might dismiss Jurgen Habermas' book on genetics, embryology and the future of human nature (Habermas, 2003) as fearful, angst-ridden speculation. But then the author is Jurgen Habermas, a seminal post war theoretician of reason through and resulting from dialogue. So how could we possibly say such a thing; how could we possibly avoid a dialogue on such matters? Or, in Rawlsian terms, how could we place these ideas outside a reasonable consensus? That this seems unthinkable means that fearful projections of a possible future take their place in the governance process, whatever their intellectual shortcomings. As Nikolas Rose argues, while:

'such concerns from philosophers and social theorists are seldom based on an examination of the realities of biomedicine'... because ... 'their dilemmas owe more to popular science predictions and speculations about even more breathtaking advances in genomic medicine, reproductive technology, neuroscience, and psychopharmacology "just around the corner" (McKibben 2003, Silver 1998, Stock 2003)... 'we need to be alert to the ways in which these predictions of fundamental transformations – imminent, but somehow always just out of reach – function in the present.' (Rose, 2007, pp. 78-79).

## 7.2 STS / SSK and New Players at the Policy Table

Barry Barnes, in debate with Brian Wynne in 2007, made the point that Government is marginalising single-issue campaigners in favour of 'the public'. But then, he asked, aren't we all, the public, us, that is, aren't most of us single issue campaigners today? Barnes also painted this picture: scientists are the old boys who sit around the policy table. Others would like to join them via the challenge to various epistemologies that are currently dominant. Scientists at the policy table become advocates of policy. Social scientists are joining the high table and acting in the same way – they join a peer group and feel they can talk about anything. Brian Wynne replied, defending his role: he wasn't there to give particular expert answers in the area of public engagement, say. Rather, he was there to ask awkward questions, particularly around the co-production of science and policy.

Barnes is nearer to the point than Wynne on this. It is a part of critical STS / SSK's failure to understand the influence of some ideas it has championed that it also struggles to accept a role it has come to play. In this section I look at critical STS / SSK's analysis and develop Barnes' point about the policy arena today.

In chapter three (section 3.6) I discussed the approaches taken by leading scientists and scientific institutions to the new patterns of governance that have

developed since the mid 1990s in particular. I argued that these can be theorised by reference to two seminal sociological and political theorists, Erving Goffman and John Rawls. This allows us to contextualise and interpret some of the novel aspects of institutional medical scientific activity since the mid 1990s as well as to think about the different levels or layers of perspectives on the changes that have occurred, particularly as expressed and presented in the public and policy domain. With this in mind, one reading of official, that is institutional-scientific, statements and approaches, or put another way, one reading of the role played by representatives of the scientific community at the policy table, is that they are sometimes an implicit, perhaps even explicit, rebuke to the more forceful views of some of the rank and file. The official statements are attempts at impression management, they are influenced by pressures to conform to a new governance consensus and they are at the same time attempts to work the governance structures to researchers' advantage.

Critical STS and SSK, focused as they are on pursuing a critique, paid insufficient attention to the subtleties of, and tacit rules guiding, natural science research practice in the areas discussed in this thesis. They also paid insufficient attention to the real and substantive changes to governance and to institutional science's adaptation to and role within new governance patterns and structures. Like the bioethicists criticised by Adam Hedgecoe, and the campaigners commonly criticised by social scientists, some critical social scientists have been guilty of

bringing a high degree of certainty to their analyses of and interventions into a messy area of practice and the complex realities of adaptation through performance. Relatedly, as I discussed at the end of chapter five, at issue is the tension between analysis and commitments (see Jasanoff, 1996, Williams, 2006).

Crudely, we might identify two strands in social science analysis. One aspires to develop a grounded and realistic sociology of medical practice (such as Dixon-Woods, Wilson, Jackson, Cavers and Pritchard-Jones, 2008). This tradition in a sense is trying to move the field back to an older tradition that worked sympathetically with clinical scientists in a context-specific way. A rather different tradition is attempting to pursue a deeper critique, concretely in the context of this PhD a critique of medical arrogance and researchers' privileges among other things. The differences are sometimes presented as disciplinary ones – such as sociology vs. bioethics, or sociology vs. post-modernism or cultural studies – but often they are contrasting approaches within sociology (Hedgecoe, 2004). However, just as critical STS / SSK's analysis of research practice and natural science researchers' role in governance is too black and white, so to claim that there is such a clear-cut demarcation, and between just two traditions, would be not only crude, but also wrong in part. For, as Barnes suggests, it is not just some kinds of social scientists that play a role at the policy table. Critical STS and SSK plays a similar role in some ways, and as we saw in chapter two with

the lengthy discussion of *Misunderstanding Science?*, critical STS and SSK positively sought such a role through the Policy Turn. This points to a failure of (self-) analysis on the part of Critical STS and SSK.

In her critique of Collins and Evans' attempt to classify expertise, to demarcate some boundaries between technical and political aspects of debates and decisions and to point to the rise of what they called the 'folk wisdom' viewpoint, Sheila Jasanoff highlighted what she regarded as the enduring importance of a different approach, one which 'invites us to take the boundaries themselves as entry points for inquiry into the relations between science and power, to ask how they come about, and what functions they serve in channelling both knowledge and politics.' From this perspective:

'The questions that loom as interesting, then, have to do with: the nature of categories and classifications (as in the influential work of Michel Foucault and Ian Hacking); with the agents, instruments and processes that produce these classifications; with patterns of inclusion and exclusion on either side of the line of expertise; and with the influence of history and culture on the drawing and redrawing of these kinds of boundaries. The project of looking at the place of expertise in the public domain appears in this light as a project in political (more particularly democratic)

theory, with epistemological questions embedded in it, but not wholly reducible to epistemology.

All this makes the kinds of distinctions that C&E try to draw between the scientific and the political phases of the decision-making (262, 276) seem at best naïve and at worst misguided.’ (Jasanoff, 2003, p. 394).

As we saw in chapter two, Jasanoff accepted that SSK ‘may reasonably be asked to cultivate a reflexive self-awareness of the ways in which our scholarly work may play out in the arenas of the “real world”’, because ‘*all* SSK scholars are necessarily engaged in an enterprise that is as deeply political as it is intellectual, even when their case studies or historical projects seem to be remote from the driving political concerns of late-twentieth-century societies.’ (Jasanoff, 1996, p. 409). However, what Jasanoff did not accept in 1996 and did not seem to want to contemplate in 2003 was that agents, instruments and processes with influence could bear some relationship to critical SSK. Brian Wynne agrees with her. When it was claimed (by others) that STS and SSK had indeed had an influence, Wynne recoiled and, as we saw in chapter one, stated in his ‘Dazzled by The Mirage of Influence?’ article that:

‘My most striking personal experience of STS engagement in policy worlds has been sheer disorientation at my failure to recognize my own

ideas in what has been celebrated as my work's public influence. In the very process of taking on influence, we are reinterpreted in ways that of course we don't control, and may not accept nor even understand. The next question hovers: can STS influence its own "influence," to limit its transformation into alien goods? Once started, the agony continues.'

(Wynne, 2007, p. 501).

And yet, like Jasanoff, Wynne seeks influence and indeed acknowledges not only that different kinds of arguments and approaches have been used by STS and SSK, but also that they should be, so long as they are kept in a relationship with each other. Unsurprisingly, coming from the perspective that he does, Wynne argues that the pragmatic policy-oriented aspects of STS and SSK should be kept in a relationship with, should be informed by, more radical thinking:

'The pragmatic should not be entirely separated from, even counter-posed to the radical. Indeed I suggest that in order to be effective, it has to be informed by a more radical cultural and historical perspective, which illuminates the sheer contingency, sometimes laughable absurdity, of what we encounter in those technoscience, social science and "policy" worlds.' (Wynne, 2007, p. 500).

The failure to gain influence (Wynne's assessment of STS and SSK's lack of



influence) could be understood as a claim that the pragmatic was in reality separated from the radical, rendering the pragmatic something different, something alien even. This denial of influence is strikingly similar to the (self-) analysis of some radical feminists, as discussed by Janet Halley and Helen Reece. If there is influence it is not really feminism (or STS / SSK). But this assessment is hard to sustain. As I argued in the introduction and as I have discussed throughout this thesis, given that some STS / SSK writers have engaged directly and indirectly with political and policy debates on the ways in which governance regimes could be changed, this body of work is of necessity shaped by this engagement. Wynne looks for signs of input into governance, while simultaneously defending the value of observance and critique. But activist STS and SSK must also be considered, in part, as an output of the construction of new forms of governance: through engagement with the political and policy process, the issues, ideas and questions addressed by these same theorists have in part been framed by those ongoing processes. To put the point another way: taking the idea of social science as an input and an output of governance processes in the round, as a whole, like everyone else who engages with politics and governance, social scientists interested in influencing governance, which includes critical STS and SSK, have in part deliberately tailored their approaches in an effort to contribute to science governance and have in part had this forced upon them through the way in which their ideas and practical activities were folded into the process.

Critical STS and SSK have highlighted a number of trends, including the meanings and values scientists bring to debates and the way that particular lines of inquiry are opened up and closed down through a focus on scientific aspects of issues and the reification of concrete and specific forms of knowledge. These points are important and of continuing relevance. However, the focus on critique, of the real and presumed institutional and cultural power of natural science, means that there is a lack of sympathy, or even interest, in natural scientists' problems; and a lack of interest in the ways in which some natural scientists have absorbed and responded to some social science analysis, even if not always in ways that social scientists anticipated or imagined. That they ignore or fail to see these changes and influences and try to separate their critical approach from their own and others' more pragmatic work has obvious intellectual shortcomings. It could be seen as a counter-hegemonic project, or perhaps it could highlight a genuine self-assessment that both the pragmatic and the critical work have had little or no influence. Radical elements in STS and SSK are very ambitious, utopian to an extent, which may have helped to blind them to the influence their ideas, in the hands of others sometimes, have had.

### 7.3 New Labour and New Modes of Governance

A number of scholars focus on Government commitment to innovation and the idea that old barriers are being broken down within what has been called the Knowledge Economy. At the start of the New Labour years, leading sociologist Anthony Giddens, architect of the 'Third Way' and proponent of 'Reflexive Modernisation', argued that expertise and expert communities undermine bureaucratic control as theorised by Weber in his idea of an 'Iron Cage'. Looking back on the period of New Labour and indeed a little further back, as I discussed at the beginning of chapter six, Duncan Wilson argues that 'if we see bioethics as a "mediating element" between politics, the public and science, then contemporary society provides it with fertile ground (Rosenberg, 1999, p. 38). The biomedical sector is increasingly seen as a prized component of the so-called "knowledge economy", with politicians and private investors placing great stock in the progress of research (Rose, 2007).' (Wilson, 2011, p. 137). Reflecting on New Labour and science, Jane Gregory and Charles Thorpe point to its enthusiasm for science and innovation and argue that it pursued this through a 'post-Fordist' policy of participation and innovation (Thorpe and Gregory, 2010; Thorpe, 2010). And finally, to return to Giddens, Alan Finlayson, in his *Making Sense of New Labour* (2003), which Thorpe and Gregory draw on substantively, places Giddens' Reflexive Modernisation alongside what he calls

think-tank Demos' 'vanguardist futurism' as defining New Labour's approach to science and modernisation.

This is a beguiling analysis, one shared in many ways by critical STS and SSK. But it is one-sided, partial. Public participation on the scale and intensity as proposed by Gregory and Thorpe barely existed in any sector or in any period under New Labour; and most certainly this kind of analysis has little to say about the very many areas of scientific research that do not naturally fit with the idea of innovation through public involvement. Wilson is right, bioethics, and as I added, STS and SSK, do play a mediating role, but this is a double-sided one, not so one dimensionally positive for the 'progress of research'. And finally, yes, New Labour did like to cultivate a relaxed and non-bureaucratic manner, and it did pursue a pattern of change, or modernisation, through problematising the professions. But many have criticised its intense interest in micro-management – attacking (some) of the old professions should not be equated with a looser, less constrained pattern of governance. It was certainly interested in innovation, but then hyper-innovation, as Moran called it, has its downsides. Contrary to Giddens' image of a fluid ever-changing landscape, some research governance under New Labour could be seen in a Weberian way. Certainly, some aspects of research have become enmeshed within tight bureaucratic control.

New Labour's approach to the governance of science can be considered a hybrid. It was defined by its engagement, rhetorically, performatively and substantively, with the Democratic Model, a model informed by themes linked to SSK and other strands of social science. There were of course many other processes in play. In practice, there was overlap in the Government's and others' treatment of distinct strands, reflecting mixed understandings, pragmatism and disparate aims at Government level.

In relation to the overall research questions I conclude that while there is much continuity between old and new forms of natural science research governance, there have been changes, and that some of these changes are the result of the work of various actors, including some STS and SSK theorists, in championing aspects of the Democratic Model. This has had some negative consequences, including: a loss of professional discretion; a less open and realistic relationship between science and society; loss of clarity about social science analysis and goals; and confusion about issues of public interest associated with scientific research and knowledge. These follow from the content of governance, but also from the way it has been developed and concretised by all the players: the pursuit of political goals via policy, structured engagement processes and 'hot topics'. A typical outcome is greater complexity and greater influence for bureaucrats and managers. That campaigners and SSK did not aim for this is largely true. That they have some responsibility for the outcome is also true.

## 7.4 Future Research

Four issues or areas could be explored to develop this thesis.

1. For a number of reasons, the UK case studies I have examined are of international significance and, as I noted in chapter one, the changes associated with the Democratic Model are thought by many to be particularly marked in the UK, making it a useful case study for analysis of changes to governance.

Comparing and contrasting developments in the UK with other countries, in particular the US and Europe, would, among other things, help to contextualise changes in the UK.

2. STS and SSK theorists have a longstanding and deep interest in expertise and governance. As we have seen, it has also been the subject of much debate and dispute within those disciplines. In parallel, to an extent, the natural scientific community and some allies have developed a keen interest and concern about what they regard as the mishandling of expertise within governance, policy worlds and the media (for a popular discussion see Mark Henderson's *The Geek Manifesto*, 2012). A social science approach that looks at how these debates are framed, by whom, how evidence or sometimes pieces of evidence circulate within these debates and, crucially, how natural scientists themselves draw upon and

use sociology of science theories would contribute a novel dimension to academic study of these questions.

3. In this thesis I have focused on critical STS / SSK and natural science research governance. In doing so I used two case studies which, while different in some key aspects regarding issues of governance, are similar to the extent that critical STS / SSK focused on the institutional power of the medical and natural scientific research community in both cases. Examination of critical STS / SSK engagement with environmentalism, an area in which STS / SSK academics sometimes ally themselves with rather than confront institutionally powerful natural science, would provide a useful point of comparison to develop the analysis further.

4. Implicitly and sometimes explicitly in my criticisms of critical STS / SSK's approach to natural science research governance, I have suggested how a more constructive engagement with natural science might be envisaged. This needs further elaboration, but based on the work conducted for this thesis it should include: more attention to the subtleties of, and tacit rules guiding, natural science research; more understanding of the real and substantive changes to governance and of the adaptation of institutional science to and its role within new governance patterns and structures; less certainty in analyses of and interventions into messy area of practice and the complex realities of adaptation through performance; greater recognition of natural scientists as fellow

researchers in the first instance, struggling to develop knowledge; and, finally, a more sympathetic (based on a more self-aware) approach to engagement in a context-specific way.



**Appendix: List of interviewees, in date order**

[Positions and job titles are given as of the date of the interview]

Dr Calum McKellar, Director of Research, Scottish Council on Human Bioethics,  
27 June 2008.

Martin Johnson, Professor of Reproductive Sciences, University of Cambridge, 3  
July 2008.

Diane Warburton, Director, Shared Practice, 3 July 2008.

Josephine Quintavalle, Founder and Director, Comment on Reproductive Ethics,  
4 July 2008.

Dr Murdo Macdonald, Policy Officer, Science, Religion and Technology Project,  
Church of Scotland, 8 July 2008.

Ian Wilmut, Chair of Reproductive Biology and Director, Scottish Centre for  
Regenerative Medicine, University of Edinburgh, 8 July 2008.

Austin Smith, MRC Research Professor in Stem Cell Biology and Director, Wellcome Trust Centre for Stem Cell Research, University of Cambridge, 11 July 2008.

John Burn, Professor of Clinical Genetics and Executive Director, Life Knowledge Park, Newcastle University, 21 July 2008.

Ian Gibson, Member of Parliament (UK), 16 October 2008.

Evan Harris, Member of Parliament (UK), 13 January 2009.

Stephen Minger, Director of the Stem Cell Biology Laboratory and Senior Lecturer, Wolfson Centre for Age Related Diseases, King's College London, 10 March 2009.

Sheila McLean, International Bar Association Chair of Law and Ethics in Medicine, and Director of the Institute of Law and Ethics in Medicine, Glasgow University, 25 March, 2010.

James Ironside, Professor of Clinical Neuropathology, University of Edinburgh, 25 March, 2010.

Peter Furness, President, Royal College of Pathologists, 31 March 2010.

Richard Sullivan, Professor in Oncology and Oncopolicy, King's College, 20 April 2010.

Hugh Whittall, Director, Nuffield Council on Bioethics, 13 May 2010.

Nick Dean, Retired (formerly Branch Head, Clinical Ethics and Human Tissue, Department of Health), 7 July 2010.

David Price, Professor of Medical Law, De Montfort University, 12 July 2010.

Margaret Brazier, Professor of Law, Manchester University, 21 July 2010.

James Wilsdon, Director, Science Policy Centre, Royal Society, 8 March 2011.

Simon Denegri, Chief Executive, Association of Medical Research Charities, 11 April 2011.

Shaun Griffin, Director of Communications and Public Affairs, Human Tissue Authority, 4 May 2011.

Joyce Tait, Professor, University of Edinburgh, Scientific Advisor to Innogen, 16 May 2011.

Catherine Lyall, School of Social and Political Science, Edinburgh University, Deputy Director, Innogen, 17 May 2011.

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